SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Agreement") is entered into as of October 2, 2005, among the United States of America, acting through the United States Department of Justice and the United States Attorney's Office for the Eastern District of Pennsylvania and on behalf of the Offices of Inspectors General of the Department of Health and Human Services ("HHS-OIG") and the Department of Veterans Affairs ("VA-OIG"), (collectively the "United States"), and King Pharmaceuticals, Inc., and Monarch Pharmaceuticals, Inc., (collectively "King" and, together with the United States, the "Parties"), through their authorized representatives.

II. PREAMBLE

As a preamble to this Agreement, the Parties recite the following:

- A. King Pharmaceuticals, which has its principal place of business in Bristol,

 Tennessee, manufactures and sells generic and branded pharmaceuticals through several whollyowned subsidiaries. The subsidiaries of King Pharmaceuticals are listed on Attachment A. For
 purposes of this Agreement, all references to King include its subsidiaries to the extent that they
 have manufactured or sold pharmaceuticals that fall within the "Covered Conduct" of this
 Agreement. The "Covered Conduct" is fully described in Paragraph I, below. King has
 manufacturing facilities in several locations in the United States, and its sales force is located
 throughout the United States. King sells its products throughout the United States, including in
 the Eastern District of Pennsylvania.
- B. Edward Bogart (the "relator") is an individual residing in the State of Tennessee.

 On March 12, 2003, the relator filed a <u>qui tam</u> action in the United States District Court for the

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Eastern District of Pennsylvania captioned <u>United States ex rel. Edward Bogart, et al. v. King Pharmaceuticals, Inc., et al.</u> (the "Civil Action"). Relator had been employed as a director of National Accounts at Monarch Pharmaceuticals from January 1998 to October 14, 2002, and he was responsible for the negotiation of certain sales agreements between Monarch Pharmaceuticals and certain customers.

- C. The Civil Action also named as plaintiffs twelve states and the District of Columbia that had, during the relevant period, state false claims act statutes (collectively, the "Plaintiff States"). This Agreement resolves the civil claims of the United States against King as set forth in Paragraph 4, below. King has entered into an agreement (the "NAMFCU Agreement") with the National Association of Medicaid Fraud Control Units ("NAMFCU") providing for, among other things, the disbursement of the State Settlement Amount (as defined in Paragraph 3, below).
- D. King sold pharmaceuticals that were purchased or reimbursed by commercial and government payors and other customers, including the Department of Health and Human Services ("HHS") and the Department of Veterans Affairs ("VA"). Each of the government customers was required by federal law to receive certain prices or pricing information, and federal law required King to pay certain rebates in connection with its pharmaceutical products.
- E. At all relevant times, the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, required participating manufacturers to pay rebates to the state Medicaid agencies pursuant to specific rules based in part, in the case of single-source and innovator multiple-source pharmaceuticals, upon the lowest price at which the manufacturer sold its products to certain commercial customers. The purpose of these specific rules is to ensure that Medicaid receives the benefit of discounts in relation to the pricing available in the commercial marketplace. King

entered into a rebate agreement with the Health Care Financing Administration ("HCFA"), now the Centers for Medicare & Medicaid Services ("CMS"), and certain of King's products were at all relevant times covered by state Medicaid plans that provided medical assistance for outpatient prescription drugs. 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(12), and 1396r-8(a)(1). Under the Medicaid Rebate Program and rebate agreement with CMS, King generally agreed: (i) to report quarterly to CMS its average manufacturer price ("AMP") and, in the case of single-source and innovator multiple-source pharmaceuticals, best price for its pharmaceutical products, as defined by 42 U.S.C. §§ 1396r-8(k)(1) and 1396r-8(c)(1)(C); and (ii) to pay quarterly rebates to the states based on the product of (a) the units of each dosage form and strength paid for under the state Medicaid plan during the rebate period as reported by the state, and (b) the greater of the difference between the AMP and best price, or minimum rebate percentage of the AMP, as further defined in 42 U.S.C. § 1396r-8(c). The states receiving Medicaid rebates are referred to in this Agreement as the "Participating States."

F. At all relevant times, King participated in the Drug Pricing Program, 42 U.S.C. § 256b, which is part of the Public Health Service ("PHS") Act, 42 U.S.C. §§ 201-300gg-92 (the "PHS Drug Pricing Program"). As a participant in the Drug Pricing Program, King entered into an agreement with HHS in connection with the pricing of its drug products sold to entities such as AIDS drug purchasing assistance programs, community health centers, hemophilia treatment centers, and certain disproportionate share hospitals, as defined in 42 U.S.C. § 256b(a)(4) ("the PHS entities"). Under the Drug Pricing Program and its agreement with HHS, King generally agreed that the amount that King required the PHS entities to pay for drug products would not exceed the AMP, as reported by King to CMS in the previous calendar quarter, minus a specified

rebate percentage that was derived, in part, from the Medicaid rebate paid by King in the preceding calendar quarter for each drug, as further described in 42 U.S.C. § 256b(a).

- G. King was party to a Master Agreement with the VA and a Federal Supply Schedule contract, number V797P-5185x. Under its agreements with the VA, King was required to make its "covered drugs" available for procurement on the Federal Supply Schedule of the General Services Administration. 38 U.S.C. § 8126(a)(1). With few exceptions, King was not allowed to charge a price for its "covered drugs" that exceeded a "Federal Ceiling Price" of 76 percent of the non-Federal AMP less an additional discount. 38 U.S.C. § 8126(a)(2). King's "covered drugs" are defined in 38 U.S.C. § 8126(h)(2). Eligible purchasers at the Federal Ceiling Price with King included the VA, the PHS, the Department of Defense ("DOD"), Indian Health Service, and the Coast Guard. 38 U.S.C. § 8126(b). In addition, King was required to disclose certain commercial pricing information to the VA in connection with its Federal Supply Schedule contract and to offer Federal Supply Schedule customers certain discounts under the contract's "Price Reductions Clause." King's Master Agreement with the VA, its Federal Supply Schedule contract, and the related legal and contractual requirements described in this paragraph are sometimes collectively referred to hereinafter as the "VA Pricing Program".
- H. King also participated in certain state rebate programs ("State Programs") that generally required a rebate separate from the Medicaid rebate for each state's utilization. The affected states were California, Connecticut, Delaware, Florida, Indiana, Massachusetts, Maryland, Maine, Minnesota, Missouri, Montana, New Jersey, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Texas, Utah, Vermont, Wisconsin, and Wyoming (referred to in this Agreement as "the State Program States"). The affected programs by state are listed in Attachment B.

- I. The United States contends that it has certain civil claims against King as specified in Paragraph 4, below, for engaging in the conduct alleged in Sections (i) through (v) of this paragraph during the period January 1, 1994, through December 31, 2002, unless otherwise specified below (the "Covered Conduct").
- (i) The United States contends that King knowingly did not collect and analyze its pricing information in a manner that ensured that King would be able to accurately determine the AMP and best price on a quarterly basis. The United States also contends that King knowingly did not adequately train its personnel to calculate accurate AMP and best price data, and that King knowingly did not provide its employees with appropriate tools, such as specialized software programs or other commonly used means for calculating Medicaid rebate payments, so that its employees could calculate AMPs and best prices accurately.
- (ii) The United States also contends that King knowingly included inappropriate customers in its retail class of trade, which resulted in inaccurate calculations of AMPs.
- (iii) The United States contends that because of the knowing misconduct alleged in Sections (i) and (ii) above, certain of King's AMP and best price calculations constituted "false records" within the meaning of 31 U.S.C. § 3729. The United States further contends that, by including such "false records" in its quarterly submissions to CMS, King failed to report accurately to CMS on a quarterly basis the AMPs and best prices, where applicable, for its pharmaceutical products, and to pay the corresponding proper amounts of Medicaid rebates resulting in an overall underpayment of Medicaid rebates for the relevant time period. Further, the United States contends that because of King's knowing misconduct with respect to certain of its pharmaceutical products, King overcharged the PHS entities, failed to deliver accurate

information to the VA and overcharged purchasers from the VA Federal Supply Schedule. The State Program States also contend that King failed to pay the proper State Program rebates, resulting in an overall underpayment of State Program rebates for the relevant time period.

- (iv) Accordingly, the United States contends that the activities alleged in Paragraph I (i) through (iii) rendered false the following claims or statements: (1) King's reports to CMS of AMPs and best prices, and the related state invoices, for the pharmaceutical products listed in Attachment C for the 36 quarters from January 1, 1994, through December 31, 2002; (2) King's charges to PHS entities for the pharmaceutical products listed in Attachment D for the period January 1, 1994, through December 31, 2002; and (3) King's charges to VA Federal Supply Schedule customers for the pharmaceutical products listed in Attachment E for the period January 1, 1994, through December 31, 2002 and pricing and other information delivered to the United States in connection with its negotiation of and performance under its Federal Supply Schedule contract and the various amendments and modifications thereto. In addition, the State Program States contend that the activities alleged in Paragraph I (i) through (iii) rendered false King's State Program invoices for the programs listed in Attachment B for the pharmaceutical products listed in Attachment F, for the period January 1, 1994, through December 31, 2002.
- (v) All other conduct of King alleged in the Civil Action is also included in the "Covered Conduct."
- J. King represents: After King received an SEC subpoena regarding various matters, the Audit Committee of King's Board of Directors initiated an independent internal investigation. When this investigation identified the deficiencies in King's AMP and best price methodologies described in Paragraph I, above, King's outside counsel retained KPMG, a nationally recognized accounting firm that, in part, specializes in health care and Medicaid

reporting. With KPMG's assistance, King undertook a comprehensive recalculation to determine the amount of King's underpayments under the Medicaid rebate program, underpayments under the State Programs, and overcharges to the PHS entities and Federal Supply Schedule customers. King and KPMG began this recalculation by compiling a database of all King transactional data (including sales, rebates and chargebacks), government utilization, customer, contract and product data relevant to the calculation of AMP, best price, Medicaid unit rebate amounts and related PHS, Federal Supply Schedule and State Program calculations for the relevant period. This data was compiled from sources that included King's sales, adjustment and chargeback records, records of amounts paid to purchasers and other payors, records of product utilization by, and rebates paid to, the state Medicaid agencies and State Programs, contracts and other agreements with pharmaceutical product purchasers, and King's historical pricing records. King and KPMG confirmed the completeness of the data they compiled by reconciling it to the net sales data in the general ledger trial balances underlying King's audited financial statements. In addition, KPMG helped King to determine the appropriate class of trade for each of the purchasers of King's pharmaceutical products.

King further represents: It re-calculated the AMPs and best prices for its pharmaceutical products from January 1, 1998, through December 31, 2002. King compared the AMPs and best prices that it had originally reported to CMS with the re-calculated AMPs and best prices. This data is contained in a summary document prepared by King, known as the Medicaid variance report, which also identifies King's total underpayment of Medicaid rebates for that period.

According to King, all AMP and best price differences between what King originally reported to CMS and the corrected AMPs and best prices are reflected in the Medicaid variance report on a product and quarter basis. In addition, King prepared variance reports reflecting its overcharges

from January 1, 1998, through December 31, 2002, to PHS entities and certain VA Federal Supply Schedule customers and its underpayments of rebates from January 1, 1998 through December 31, 2002 to the State Program States. In addition, King used the results of the recalculation for the 1998 to 2002 period to determine by extrapolation Medicaid, PHS, VA Federal Supply Schedule and State Program variances for all King products with utilization under the applicable program for the period from January 1, 1994 through December 31, 1997.

- K. King represents that it has performed the review and calculations and prepared the variance reports described in Paragraph J, above in good faith and that it believes that such calculations and variance reports are complete and accurate in all material respects. King acknowledges that the United States considered, among other things, the variance reports described in Paragraph J, above, and other information provided by King in its settlement of the Covered Conduct.
- L. The United States contends that it also has certain administrative claims, as specified in Paragraph 6, below, against King for the Covered Conduct.
- M. This Agreement is made in compromise of disputed claims. It is neither an admission of liability by King nor a concession by the United States that its claims are not well founded. King expressly denies the allegations of the United States and the relator as set forth herein and in the Civil Action and denies that it has engaged in any wrongful conduct in connection with the Covered Conduct. Neither this Agreement, its execution, nor the performance of any obligations under it, including any payments, nor the fact of the settlement, is intended to be, or shall be understood as, an admission of liability or wrongdoing, or other expression reflecting upon the merits of the dispute by King.

N. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, the Parties reach a full and final settlement pursuant to the Terms and Conditions below.

III. TERMS AND CONDITIONS

- 1. King agrees to pay to the United States, the Plaintiff States, the Participating States, and the State Program States, collectively, \$124,057,318, with interest accrued to the date that King makes the payment provided for in Paragraph 2, below (the "Settlement Amount"). King has also agreed that this interest accrues at 3.75 percent per annum from July 1, 2005. The Settlement Amount shall constitute a debt immediately due and owing on the Effective Date of this Agreement (as defined in Paragraph 21, below).
- 2. Of the Settlement Amount in Paragraph 1, above, King and the United States agree that the sum of \$73,420,225, with accrued interest, shall represent the federal share of the Settlement Amount (the "Federal Settlement Amount"). The Federal Settlement Amount includes all amounts payable in respect of the federal share of the Medicaid Rebate Program, the VA Pricing Program and the PHS Drug Pricing Program. With respect to the first two programs, King agrees to make an electronic funds transfer of the Federal Settlement Amount in accordance with the written instructions to be provided by the Department of Justice. King agrees to make such transfer no later than ten business days following the Effective Date (as defined in Paragraph 21, below).

With respect to the PHS Drug Pricing Program, King agrees to transfer the portion of the Federal Settlement Amount payable to the PHS entities listed on Attachment G into a segregated bank account (the "PHS Settlement Account") no later than ten business days following the Effective Date (as defined in Paragraph 21 below). As will be provided in written instructions from the United States, King will disburse the amount transferred into the PHS Settlement

Account to the individual PHS entities listed on Attachment G within thirty days following the Effective Date (as defined in Paragraph 21, below).

- 3. Of the Settlement Amount in Paragraph 1, above, King, the Plaintiff States, the Participating States, and the State Program States (collectively, the "States") have agreed that the sum of \$50,637,093, with accrued interest as provided in Paragraph 1, above, shall represent the state share of the Settlement Amount (the "State Settlement Amount"). King agrees to transfer the State Settlement Amount in accordance with the provisions of the NAMFCU Agreement and the individual state settlement agreements referred to therein (the "State Settlement Agreements").
- 4. Subject to the exceptions in Paragraph 5, and subject to Paragraph 15, below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement), and in consideration of the obligations of King set forth in this Agreement, the United States, on behalf of itself, its officers, agents, agencies, and departments, agrees fully and finally to release King, its past and present parents, corporate affiliates, divisions, and subsidiaries, and each of their predecessors, subsidiaries, successors and assigns (the "King Corporate Entities"), and, except as provided in Paragraph 5, below, their past and present directors, officers, agents and employees (together with the King Corporate Parties, the "King Released Parties"), from any civil or administrative monetary claim that the United States has or may have under the False Claims Act, 31 U.S.C. §§ 3729-3733, the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812, the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8, the Drug Pricing Program, 42 U.S.C. § 256b, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, § 603 of the Veterans Health Care Act of 1992, 38 U.S.C. § 8126, any statutory provision applicable to the programs in this Agreement for which the Civil Division, United

States Department of Justice, has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part 0, Subpart I, § 0.45(d) (1995), and common law claims, including claims for fraud, unjust enrichment, payment by mistake, or breach of contract, for the Covered Conduct.

- 5. Notwithstanding any term of this Agreement, the United States specifically does not in this Agreement release King and the other King Released Parties from any and all of the following: (a) any criminal, civil, or administrative liability arising under Title 26, United States Code (Internal Revenue Code); (b) any criminal liability; (c) any liability to the United States (or any agencies thereof) for any conduct other than the Covered Conduct; (d) any liability based upon obligations created by this Agreement; (e) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs; (f) any express or implied warranty claims or other liability for defective or deficient products and services provided by King; (g) any liability based on a failure to deliver items or services due; (h) any civil liability against individuals, if they have received written notification that they are the "target" of a criminal investigation (as defined in the U.S. Attorneys' Manual), have been indicted, charged or convicted, or have entered into a plea agreement, in each case related to the Covered Conduct; and (i) except as expressly stated in this Agreement, any administrative liability against individuals, including current and former directors, officers, and employees of King and the other King Corporate Entities.
- 6. In consideration of the obligations of King set forth in this Agreement and the Corporate Integrity Agreement ("CIA") referred to in Paragraph 19, below, and incorporated by reference into this Agreement, subject to Paragraph 15, below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement), and conditioned on payment of the Federal Settlement Amount, HHS-OIG agrees to release and

refrain from instituting, directing or maintaining any administrative action seeking exclusion from the Medicare, Medicaid, or other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against King and each other King Corporate Entity under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law), or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities), for the Covered Conduct, except as reserved in Paragraph 5, above, and as reserved in this paragraph. HHS-OIG expressly reserves all rights to comply with any statutory obligations under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) to exclude King from the Medicare, Medicaid, or other Federal health care program based upon the Covered Conduct. Nothing in this paragraph precludes HHS-OIG from taking action against entities or persons, or for conduct and practice, for which claims have been reserved in Paragraph 5, above.

- 7. The United States will file a motion to dismiss the federal count of the Civil Action promptly following execution of this Agreement; however, the motion will provide that dismissal with prejudice will not occur until King has transferred the applicable portions of the Federal Settlement Amount to the United States and into the PHS Settlement Account, as described in Paragraph 2, above.
- 8. King waives and will not assert any defenses King may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

 Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by

the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

- 9. King, on behalf of itself and the other King Corporate Entities, fully and finally releases, waives, and discharges the United States, its agencies, employees, servants, and agents from any claims (including attorneys' fees, costs and expenses of every kind and however denominated) which King or any other King Corporate Entity has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to or arising from the United States' investigation and prosecution of the Covered Conduct.
- 10. The Settlement Amount that King must pay pursuant to this Agreement shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicaid program payor, or any State payor, or any other government payor; and, if applicable, King agrees not to resubmit to any Medicaid program, state payor, or any other government payor any previously denied claims, which denials were based on the Covered Conduct, and agrees not to appeal any such denials of claims.
 - 11. King agrees to the following:
- a. <u>Unallowable Costs Defined</u>: that all costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47, and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf of King or any other King Released Party in connection with the following shall be "unallowable costs" on government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program ("FEHBP"): (1) the matters covered by this Agreement; (2)

the United States' audit and civil investigation of the matters covered by this Agreement; (3) King's investigation, defense, and corrective actions undertaken in response to the United States' audit and civil investigation in connection with the matters covered by this Agreement (including attorneys' fees); (4) the negotiation and performance of this Agreement; (5) the payment King makes to the United States pursuant to this Agreement and any payments that King may make to the relator, including costs and attorneys' fees; and (6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS. Nothing, however, in Subparagraph a(6) of this paragraph affects the status of costs that are not allowable based on any other authority applicable to King.

- b. <u>Future Treatment of Unallowable Costs</u>: These unallowable costs shall be separately determined and accounted for by King, and King shall not charge such unallowable costs directly or indirectly to any contracts with the United States or any state Medicaid program, or seek payment for such unallowable costs through any cost report, cost statement, information statement, or payment request submitted by King or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- c. Treatment of Unallowable Costs Previously Submitted for Payment: King further agrees that within 90 days of the Effective Date of this Agreement, it shall identify to applicable Medicaid, State, and VA fiscal agents, any unallowable costs (as defined in this paragraph) included in payments previously sought from the United States, or any State Medicaid Program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by King or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements,

information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. King agrees that the United States, at a minimum, shall be entitled to recoup from King any overpayment plus applicable interest and penalties as a result of the inclusion of such unallowable costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice, and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by King or any of its subsidiaries or affiliates on the effect of inclusion of unallowable costs (as defined in this paragraph) on King or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

- d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine King's books and records to determine that no unallowable costs have been claimed in accordance with the provisions of this paragraph.
- 12. This Agreement is intended to be for the benefit of the Parties only, and, except to the extent expressly provided in Paragraph 13, below, by this instrument the Parties do not release any claims against any other person or entity other than King and the other King Released Parties.
- 13. King agrees that it shall not seek payment for any of the monies owed under this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third-party payors. King waives any causes of action against these beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims for payment covered by this Agreement. Nothing in this Paragraph 13 shall affect King's

rights to recover amounts due under agreements with non-governmental third parties, including sellers and manufacturers of pharmaceutical products to whom King previously has paid royalties, co-promotion fees or other amounts determined directly or indirectly by reference to the net sales of King's products.

- 14. King expressly warrants that it has reviewed its financial situation and that it is currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and that it is not aware of any reasonably foreseeable circumstances under which it would not remain solvent following payment of the Settlement Amount. Further, the Parties expressly warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth in this Agreement constitute a contemporaneous exchange for new value given to King, within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended and do, in fact, represent a reasonably equivalent exchange of value which is not intended to hinder, delay, or defraud any entity to which King was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).
- 15. If within 91 days of the Effective Date of this Agreement or of any payment made hereunder, King commences, or a third party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, (a) seeking to have any order for relief of King's debts, or seeking to adjudicate King as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for King or for all or any substantial part of King's assets, King agrees as follows:

- a. King's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. §§ 547 or 548, and King will not argue or otherwise take the position in any such case, proceeding, or action that: (i) King's obligations under this Agreement may be avoided under 11 U.S.C. §§ 547 or 548; (ii) King was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment of the Settlement Amount; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to King.
- b. If King's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement, and bring any civil and/or administrative claim, action, or proceeding against King for the claims that would otherwise be covered by the releases provided in Paragraphs 4 and 6, above. King agrees that (i) any such claims, actions, or proceedings brought by the United States (including any proceedings to exclude King from participation in Medicare, Medicaid, or other Federal health care programs) are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceeding described in the first clause of this paragraph, and that King will not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) King will not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding which are brought by the United States within 90 calendar days of written notification to King that the releases have been rescinded pursuant to this paragraph, except to the extent such defenses were available on the Effective Date; and (iii) King will not contest the United States' assertion that it

has a valid claim against King in the amount of \$186,085,977 and which may be subject to penalties of \$5,000 to \$10,000 for each false claim submitted to an agency of the United States or caused to be submitted to an agency of the United States, and the United States may pursue its claim in the case, action, or proceeding referenced in the first clause of this paragraph, as well as in any other case, action, or proceeding.

- c. King acknowledges that its agreements in this paragraph are provided in exchange for valuable consideration provided in this Agreement.
- 16. Each party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 17. King represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.
- 18. This Agreement is covered by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement shall be the United States District Court for the Eastern District of Pennsylvania, except that disputes arising under the CIA incorporated herein by reference shall be resolved exclusively through the dispute resolution provisions set forth in the CIA.
- 19. King has entered into the CIA with HHS-OIG, attached as Attachment H, which is incorporated by reference into this Agreement. King will immediately upon the execution of the CIA begin to implement its obligations under the CIA.
- 20. The undersigned King signatories represent and warrant that they are authorized by their respective Boards of Directors to execute this Agreement. The undersigned United States signatories represent that they are signing this Agreement in their official capacities and they are authorized to execute this Agreement through their respective agencies and departments.

- 21. As used in this Agreement, the "Effective Date" shall mean the first business day on which the later of the following events shall have taken place: (1) this Agreement has been fully executed by all the Parties; and (2) the district court has granted the motion to dismiss described in Paragraph 7 of this Agreement and has entered an appropriate order.
- 22. The Parties acknowledge that their respective rights and obligations under this Agreement are not dependent upon the consummation of the NAMFCU Agreement or the State Settlement Agreements, including in the event that such other agreements do not receive any required court approval. Notwithstanding anything herein to the contrary, King's obligation to pay the State Settlement Amount, or any individual State's share thereof, shall arise only under the NAMFCU Agreement and the State Settlement Agreements, and this Agreement shall not create any presumption that King has any liability to any state, or as to the amount of any such liability that may be found to exist.
- 23. King contends that beginning with its calculations and reports for products utilized in the first quarter of 2003 it has been calculating and reporting AMP for its pharmaceutical products using a methodology that has resulted in it overpaying its quarterly rebates to Medicaid and to state rebate programs. Nothing in this Agreement shall limit King's right to pursue recovery of any overpayments that may have resulted from its use of this methodology from the United States, the state Medicaid agencies or the state rebate programs, and nothing in this Agreement shall limit the right of the United States or any state Medicaid agency or rebate program to contest any such recovery.
- 24. This Agreement shall be binding on all successors, transferees, heirs, and assigns to the Parties.

- 25. This Agreement, together with the CIA incorporated by reference, constitutes the complete agreement between the Parties with regard to the Covered Conduct. This Agreement may not be amended except by written consent of the Parties, except that the CIA may be modified with only the mutual written consent of King and HHS-OIG.
- 26. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which taken together shall constitute one and the same Agreement.

 Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

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THE UNITED STATES OF AMERICA

DATED: 10/31/05	BY: Tatuel Whenhe
DATED: 10/31/05	BY: VIRGINIA A. GIBSON Assistant United States Attorney Chief, Civil Division
DATED: 10/31/05	BARBARA ROWLAND Assistant United States Attorney
DATED:	BY: SANJAY BHAMBHANI Trial Attorney United States Department of Justice – Civil Division, Commercial Litigation, Fraud Section
DATED:	BY: LEWIS MORRIS Chief Counsel to the Inspector General Office of Inspector General United States Department of Health and Human Services

THE UNITED STATES OF AMERICA

DATED:	BY:	
•		PATRICK L. MEEHAN
	,	United States Attorney
DATED:	BY:	
		VIRGINIA A. GIBSON
·		Assistant United States Attorney
		Chief, Civil Division
DATED:	BY:	
DIVINO	D1.	BARBARA ROWLAND
		Assistant United States Attorney
•		()
1.1-		X IX
DATED: 10/24/05	BY:	
		SANJAY BHAMBHANI
		Trial Attorney
		United States Department of Justice - Civil Division, Commercial Litigation, Fraud
		Section
		2-2
DATED:	BY:	I BUILD LODDIG
		LEWIS MORRIS Chief Councel to the Inspector General
		Chief Counsel to the Inspector General Office of Inspector General
		United States Department of Health and
		Human Services
		•

THE UNITED STATES OF AMERICA

DATED:	BY:	
		MEEHAN s Attorney
DATED:		A. GIBSON nited States Attorney Division
DATED:	BARBARA	ROWLAND nited States Attorney
DATED:	Trial Attorn United State	HAMBHANI ley es Department of Justice – Civil ommercial Litigation, Fraud
DATED: 10/28/05	Office of In United State	DRRIS sel to the Inspector General espector General es Department of Health and

KING PHARMACEUTICALS, INC. MONARCH PHARMACEUTICALS, INC.

DATED:	10/31/05	BY:	EXECUTIVE SIGNATORY King Pharmaceuticals, Inc.
DATED;	10/31/05	BY:	EXECUTIVE SIGNATORY Monarch Pharmaceuticals, Inc.
DATED:	10/31/05	BY:	Man 9. P MARC ROSENBERG, ESQ. Cravath, Swaine & Moore LLP

Attachment A

King Pharmaceuticals of Nevada, Inc.
King Pharmaceuticals Research and Development, Inc.
Gentrac, Inc.
JMI-Daniels, Inc.
Meridian Medical Technologies, Inc.
Brunswick Biomedical Investment Corporation
STI International Limited
Meridian Medical Technologies Limited
Monarch Pharmaceuticals, Inc.
Monarch Pharmaceuticals of Ireland Limited
Parkedale Pharmaceuticals, Inc.
Jones Pharma Incorporated
Daniels Pharmaceuticals, Inc.

California ADAP

California COHS

California FPACT

California Unknown

Connecticut ADAP

Connecticut PACE

Connecticut SAGA
Connecticut Unknown

Delaware PA

Delaware SRP

Delaware Unknown

Florida Senior Rx

Indiana AIM

Indiana Unknown

Maine ADAP

Maine ERP

Maine LCDE

Maine Unknown

Maryland KDP

Maryland PAP

Maryland Unknown

Massachusetts ACH

Massachusetts DEL

Massachusetts SPP

Massachusetts Unknown

Minnesota ADAP

Minnesota PDP

Minnesota SD

Minnesota Unknown

Missouri ADAP

Missouri Senior Rx

Montana Unknown

New Jersey ADAP

New Jersey ADRP

New Jersey PAAD

New Jersey SG

New Jersey Unknown

New York ADAP

New York DS

New York EAC

New York EPIC

New York HHR

New York HR

New York MDP

New York Unknown

North Carolina Unknown

[[NYCORP:2547823]]

Oregon ADAP

Pennsylvania ESRD

Pennsylvania GA

Pennsylvania PACE

Pennsylvania PB

Pennsylvania Unknown

Rhode Island PAE

Rhode Island Unknown

Texas CHIP

Texas CIDC

Texas CSHCN

Texas KH

Utah ADAP

Vermont Script

Wisconsin CD

Wisconsin SC 200

Wisconsin Unknown

Wyoming ADAP

Wyoming MMP

ACETAMINOPHEN

ADRENALIN

ALTACE

AMANTADINE

ANEXSIA

ANUSOL

APLISOL

AVC

BARIUM

BICILLIN

BREVITAL

BROMPHEN

BROMPHENIRAMINE

CHLORAMPHENICOL

CHLOROMYCETIN

CODEINE

COLY-MYCIN

CORGARD

CORTISPORIN

CORZIDE

CYTOMEL

DELESTROGEN

DRIZE-R

ENDAGEN

FLORINEF

FLUOGEN

FLUPHENAZINE

GUAIFENESIN

HCBT/APAP

HISTOPLASMIN

HUMATIN

HYDROCODONE

HYDROCORTISONE

KEMADRIN

KETALAR

KETAMINE

KGDAL

KGFED

KGHIST

LEVOXYL

LORABID

MANTADIL

MENEST

MONAFED

MORPHINE

NASABID

[[NYCORP:2547823]]

NEOPOLYMYXIN

NEOSPORIN

NORDETTE

NUCOFED

ORTHO-PREFEST

OTOCAIN

OXYCODONE

PAPAVERINE

PEDIOTIC

PENICILLIN

PHENIRAMINE

PHENOBARBITAL

PHENTERMINE

PITOCIN

PITRESSIN

POLYSORIN

POLYSPORIN

PROCANBID

PROCTOCORT

PROLOPRIM

QUIBRON

SEPTRA

SILVADENE

TAPAZOLE

THALITONE

THEREVAC

THIOMALATE

THROMBIN

THYROID

TIGAN

TUSSEND

TUSSIGON

TUSSIN

VANEX

VIRA-A

VIROPTIC

WYCILLIN

ACETAMINOPHEN

ADRENALIN

ALTACE

AMANTADINE

ANEXSIA

ANUSOL

APLISOL

AVC

BARIUM

BICILLIN

BREVITAL

BROMPHEN

BROMPHENIRAMINE

CHLORAMPHENICOL

CHLOROMYCETIN

CODEINE

COLY-MYCIN

CORGARD

CORTISPORIN

CORZIDE

CYTOMEL

DELESTROGEN

DRIZE-R

ENDAGEN

FLORINEF

FLUOGEN

FLUPHENAZINE

GUAIFENESIN

HCBT/APAP

HISTOPLASMIN

HUMATIN

HYDROCODONE

HYDROCORTISONE

KEMADRIN

KETALAR

KETAMINE

KGDAL

KGFED

KGHIST

LEVOXYL

LORABID

MANTADIL

MENEST

MONAFED

MORPHINE

NASABID

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NEOPOLYMYXIN

NEOSPORIN

NORDETTE

NUCOFED

ORTHO-PREFEST

OTOCAIN

OXYCODONE

PAPAVERINE

PEDIOTIC

PENICILLIN

PHENIRAMINE

PHENOBARBITAL

PHENTERMINE

PITOCIN

PITRESSIN

POLYSORIN

POLYSPORIN

PROCANBID

PROCTOCORT

PROLOPRIM

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SILVADENE

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ACETAMINOPHEN

ADRENALIN

ALTACE

AMANTADINE

ANEXSIA

ANUSOL

APLISOL

AVC

BARIUM

BICILLIN

BREVITAL

BROMPHEN

BROMPHENIRAMINE

CHLORAMPHENICOL

CHLOROMYCETIN

CODEINE

COLY-MYCIN

CORGARD

CORTISPORIN

CORZIDE

CYTOMEL

DELESTROGEN

DRIZE-R

ENDAGEN

FLORINEF

FLUOGEN

FLUPHENAZINE

GUAIFENESIN

HCBT/APAP

HISTOPLASMIN

HUMATIN

HOMATIN

HYDROCODONE

HYDROCORTISONE

KEMADRIN

KETALAR

KETAMINE

KGDAL

KGFED

KGHIST

LEVOXYL

LORABID

MANTADIL

MENEST

MONAFED

MORPHINE

NASABID

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NEOPOLYMYXIN

NEOSPORIN

NORDETTE

NUCOFED

ORTHO-PREFEST

OTOCAIN

OXYCODONE

PAPAVERINE

PEDIOTIC

PENICILLIN

PHENIRAMINE

PHENOBARBITAL

PHENTERMINE

PITOCIN

PITRESSIN

POLYSORIN

POLYSPORIN

PROCANBID

PROCTOCORT

PROLOPRIM

I KOLOI KIN

QUIBRON

SEPTRA

SILVADENE

TAPAZOLE

THALITONE

THEREVAC

THIOMALATE

THROMBIN

THYROID

TIGAN

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TUSSIGON

TUSSIN

VANEX

VIRA-A

VIROPTIC

WYCILLIN

ACETAMINOPHEN

ADRENALIN

ALTACE

AMANTADINE

ANEXSIA

ANUSOL

APLISOL

AVC

BARIUM

BICILLIN

BREVITAL

BROMPHEN

BROMPHENIRAMINE

CHLORAMPHENICOL

CHLOROMYCETIN

CODEINE

COLY-MYCIN

CORGARD

CORTISPORIN

CORZIDE

CYTOMEL

DELESTROGEN

DRIZE-R

ENDAGEN

FLORINEF

FLUOGEN

FLUPHENAZINE

GUAIFENESIN

HCBT/APAP

HISTOPLASMIN

HUMATIN

HYDROCODONE

HYDROCORTISONE

KEMADRIN

KETALAR

KETAMINE

KGDAL

KGFED

KGHIST

LEVOXYL

LORABID

MANTADIL

MENEST

MONAFED

MORPHINE

NASABID

[[NYCORP:2547823]]

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NEOPOLYMYXIN

NEOSPORIN

NORDETTE

NUCOFED

ORTHO-PREFEST

OTOCAIN

OXYCODONE

PAPAVERINE

PEDIOTIC

PENICILLIN

PHENIRAMINE

PHENOBARBITAL

PHENTERMINE

PITOCIN

PITRESSIN

POLYSORIN

POLYSPORIN

PROCANBID

PROCTOCORT

PROLOPRIM

QUIBRON

SEPTRA

SILVADENE

TAPAZOLE

THALITONE

THEREVAC

THIOMALATE

THROMBIN

THYROID

TIGAN

TUSSEND

TUSSIGON

TUSSIN

VANEX

VIRA-A

VIROPTIC

WYCILLIN

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Abbeville County Health Dept

Access Community Health Network

Addison County Health Dept

Adult & Child Health (cab For HIth

Adventist Majuro Hospital

Adventist Majuro Hospital

Aids Arms Inc

Aids Healthcare Foundation

Aids Healthcare Foundation

Aids Healthcare Foundation

Aids Healthcare Foundation

Akron Health Department

Ala D/H Cherokee County/TB

Ala D/H Dallas Cty/TB

ALA D/H Greene Cty/TB

Ala D/H Lee County/TB

Ala D/H Monroe Cty/TB

Alamance County Hospital

Alameda - Eastmont Wellness Center

Alameda - Hayward Health Center

Alameda - Newark Health Center

Alameda Co Dept of Health

Alameda County Medical Center

Albany Cty Mntl Hlth Clinic

Alexander Co Health Dept

Alexander, Vicki Ann MD

Alexandria Health Department Pharma

Allegany County Health Dept

Allen County Health Dept

Allentown Bureau of Health

Alma Illery Medical Center

Ammonoosuc Community Hlth Svs

Anchorage Neighborhood Health Cl

Anchorage Neighborhood Health/

Andrew County Health Dept

Angle, Marcia A MD

Anne Arundel County Government

Anson Cty Health Department

Antonio Delacruz

Appalachia Health District

Appalachian District Health Departm

Arasu, Gopinath MD

Area Health Development Board, Inc.

Arizona Dept of Health Serv, STD Section

Arkansas Dept. of Health

Arlington Comm Clin Pharmacy

Arsenal Health Center A/B/of

Asche Inc Pharmacy of

Ashe County Health Department

Atlantic City Med Ctr Pharm

Atlantic City Medical Center

Atlantic Medical Center, Inc

Atlanticare Medical Center

Audrain County Health Unit

Aurora Sinai Medical Center, Inc.

Autauga County Health Dept.

Bacon, Janice E MD

Baldwin Co Health Department

Baldwin Co. Health Dept

Baltimore City Health Dept

Baltimore City Hlth Dept Cshs

Baltimore City Hith Dept DFHC

Baltimore Medical System, Inc.

Barbour County Health Dept

Barbour County Health Dept.

Barnes Kasson Hospital

Barnwell Co Health Department

Barnwell County Health Dept

Barnwell County Health Dept.

Barren River District

Barringer Pharmacy

Barringer Pharmacy

Barry County Health Dept

Barton County Health Dept

Bashas' United Drug, #55 (contracted pharmacy)

Bates County Health Department

Bay Medical Center

Beaufort County Health Dept

Beaufort County Health Dept.

Beaufort-Jasper Comp Health

Behaviorial Health Center

Bellevue Hospital Center - Hhc

Benjamin, Robert Aaron MD

Bentaubgeneralhospital

Benton County Health Dept

Benton-Franklin Dist Hth Dept

Berkeley Vd Health Clinic

Bernalillo County Sw Hlth Fld

Bertie County Health Dept

Bexar County Hospital District

Bibb County TB Program

Birmingham Dept of Health

Blackburn Community Hlth Ctr

Bladen County Health Departmen

Blanchard, Patricia S NP

Blount Co Health Department

Blue Ridge Medical Center, Inc.

Bluitt-Flowers Health Center

Bollinger County Health Ctr

Bond Community Health Center

Boston Health Care For The Homeless

Boston Medical Center

Boston Medical Center - Newton Stre

Boston Medical Center Intptn

Bowling Green Warren Co Hlth C

Boydton Medical Center

Boydton Medical Center

Brackenridge Hospital

Brackenridge Hospital

Brackenridge Hospital Phcy

Brexton Chase MD Office

Broadlawns Medical Center

Broadlawns Medical Center

Brooks Pharmacy 335

Broome County Health Dept

Broward Chd

Broward Co Health Department

Broward County Health Department

Brunswick Co Health Dept Nestd

Brunswick Co Health Dept-FP

Bullet County Health Department

Bullock County Health Dept.

Burgess Health Center

Butler Co Health Department

Buttonwillow Health Center

Cabarrus Health Alliance

Cabarrus Health Alliance

Caldwell Co Health Department

Caldwell County Health Department

Calhoun County Health Dept.

Cambridge Heatlh Alliance Abo

Camden On Gauley Med Ctr, Pharm

Camuy Health Services, Inc

Camuy Health Services, Inc

Cantner's Drug Store

Canyonlands Health Care

Capitol Diaylsis

Carolina Medical Center Northpark Pharmacy

Carolinas Medical Center

Carolinas Medical Center

Carolinas Medical Center

Carolyn Stith Clinic Pharmacy

Carpenter, S Gayle Do

Carroll, John R MD

Cass County Health Dept

Cassandra Beatty, M.D.

Castaner General Hospital, Inc

Caswell County Health Dept.

Catahoula Parish Medical Ctr

Catawba County Health Dept

Cdt Playa

Cent.de Servicios Prim.de Salud

Center For Mental Health Pharmacy

Centerville Clinics Inc

Central Florida Health Care

Central Florida Healthcare

Central Georgia Medical Ctr

Central North Alabama Health Servic

Centro De Salud De Lares

Centro De Salud Familiar

Centro De Salud Familiar

Centro Salud Familiar

Cermak Health Services

Chamber County Health Dept

Chambers County Health Dept

Chang, Carlos Felipe MD

Channel Medical Center Phmcy

Channel Pharmacy

Charles County Health Dept.

Charles Davis

Charles Drew Health Center

Charles Drew Health Center

Charles, Ronald A MD

Charleston Co Health Departmen

Charleston Co. Health Dept.

Charleston Memorial Hospital

Charleston Memorial Hospital

Chatham County Health Dept

Chautauqua Co Health Dept

Chemist Shop (contracted pharmacy)

Chesterfield County Health Dept

Chesterfield County Health Dept.

Childrens Hospital Pharmacy

Chilton Co Health Department

Chiricahua Community Health Ce

Choctaw Co Health Department

Choptank Community Health

Choptank Community Health Caroline

Chowan County Health Dept

Christopher, Kim L Np

Christus - St. Michael Health Syste

Christus Spohn Memorial Hosp

Chu, Michael M A MD

Church Health Center

Ciales Primary Health Care

Citizen Health Corp Phcy

City of Baltimore

City of Chicago, Department of Proc

City of Detroit Health Department

City of Long Beach Health Dept

City of Saint Louis

City of Toledo, Dept of Hlth

City-County Health Dept.

Clackamas County Public Health

Clarian Health Partners, Inc.

Clark County Health Dept

Clark County Health District

Clarke County Health Dept - TB

Clay Co. Health Department

Clay County Health Department

Clay County Health Department

Cleburne Co Health Department

Cleveland Clinic Pharmacy

Clinch River Pharmacy

Clinica Adelante-buckeye

Clinica Campesina

Clinica Compesina Family Health

Clinica Msr Oscar A Romero

Clinicas De Salud Del Pueblo

Cloud County Health Department

Cloverfork Clinic

Cmc Biddle Point Pharmacy

Cmc Myers Park Pharmacy

CMC Myers Park Pharmacy

Cmc-biddle Point

Cmc-north Park

Coastal Family Health Center

Coastal Family Hlth Center

Coats, Rebecca A MD

Coconino County Public Health

Coffee County Health Dept.

Coh-Health & Human Services

Colbert County Health Dept.

Cole County Health Dept

Colleton County Home Health - Sc Dh

Collier Health Services Inc

Collier Health Services, Inc

Columbia Basin Health Assoc

Columbia Basin Health Association

Columbia Health Center

Columbia Valley Community Hlth

Columbine Family Health Ctr

Columbine Family Health Ctr

Columbus Ambulatory Healthcare Serv

Columbus County Health Dept

Columbus Neighborhood Health

Columbus Northeast Health Cntr

Colusa County Health Dept

Comm HIth And Soc Svcs (chass)

Commonwealth of Puerto Rico

Communicable/HIV Drugs

Communicable/Immunizations

Communicable/STD Drugs

Community Care Pharmacy

Community Health Care

Community Health Care, Pharmac

Community Health Center

Community Health Center

Community Health Centers

Community Health Centers

Community Health Centers, Inc

Community Health Foundation

Community Health Improvement C

Community Health of S. Dade, Inc

Community Health of South Dade

Community Health of South Dade

Community Health Partners

Community Health Pharmacy

Community Health Services Inc

Community Hlth Svcs Pharmacy

Community Medical Center

Comprecare Health Center Pharm

Comprehensive Health Ctr, Inc

Comprehensive Health Pharmacy

Concilio De Salud Integral De

Concilio De Salud Integral De

Conecuh County Health Department Cl

Constant Care Clinic Pharmacy

Contra Costa Regional Medical

Cook County HIV Primary Care

Cook County Hospital

Cook County Hospital Pharmacy

Cooper County Nursing Service

Coosa Health Department

Cornerstone Medical Center

Corp Serv Integrales De Salud

Corp Serv Integrales De Salud Corp Serv Integrales Salud, In

Corp Serv Integrales Salud, In

Corp Servicios Integrales De

Corp Servicios Integrales De

Corporacion De Servicios

Correctional Health Services Pharma

Cossma-corp.de Salud A Migrantes

Cottage Corner Community

Cottage Corner Health

Coughlin, Brenda Marie W MD

Country Doctor Community Clini

Country Doctor Community Clini

County of Humbolt

County of Santa Cruz

County of Santa Cruz Hlth Svc

Covington Co Health Dept.

Cowley County Health Dept.

Craig, Allen Scott MD

Craig's Drug Store Inc

Crater Health District Pharmacy

Craven County Health Department

Crawford County Memorial Hospital

Crawford County Public Health

Crenshaw Co Public Health Dept

Crook County Health Dept

Cross Timbers Health Clinics,inc

Crozer-chester Medical Center

Crusaders Central Clinic Assoc

Crusaders West End Pharmacy

Crusaders West End Pharmacy

Crusaders West End Pharmacy

Crusaders West End Pharmacy

Cullman Co. Health Dept.

Cumberland County Health Dept.

Cumberland Hospital - Hhc

Curry County Health Dept

CVS Procare Pharmacy #2921 (contracted pharmacy)

DAW Inc

Dale Co Health Department

Dallas Co Health Dept

Dallas Co Health Dept

Dallas County Health Dept

Dallas County Health Dept

Dare County Health Dept

Darren Matchell, M.D.

Daughters of Charity Community

Dave's Eagle Super Market, Inc

David Powell Clinic Pharmacy

Davidson County Health Dept

Daviess County Health Dept.

De La Torre, Laura Elias MD

Decatur County Health Dept

Deharo-Saldivar Health Ctr

Dekalb Co Health Department

Dekalb County Board of Health

Delta Community Hlth Ctr, Inc

Delta County Health Dept

Dent County Health Department

Denver Health Medical Center

Department of Health

Department of Health Services

Department of Public Health

Dept of Health Services, human Res C

Dept of Public Health - CT

Deschutes County Health Dept

Detroit Receiving & University Heal

Dhr District 7 - West Central Hlth

Dhr District 7- Columbus Health Dept

Dhr District 8, Unit 2

Dhr District 9, Unit 3

Di Lillo, Louis MD

Dickson County Health Dept

Diego, Silvia Margarita MD

District Health Dept #4

Doctor's Choice Pharmacy, Inc

Dolores County Health Assoc

Dooley, Parker C MD

Dover Health Center

Downtown Health Plaza Downtown Health Plaza Dr Gajewski Pharmacy/erie County Duke University Medical Center Duplin County Health Departmen Durham County Health Dept Pharmacy Dutchess County Health Dept. Duval County Dept of Hlth-**Duval County Health Department Duval County Public Health** E & W Perlman Ambulatory Care E Valley Community Health Cent Earl K Long Medical Center East Arkansas Family Hlth Cntr East Boston Neighborhood Health East Dallas Health Center East Metro Health District East New York Diagnostic & Treatmen Eastside Health Center Phcy Eau Claire Cooperative Health Cente Ebeye Hospital Econo Drug (contracted pharmacy) Edgecombe County Health Department Edisto Health District Edward Roybal Chc El Rio Santa Cruz Neighborhood Ellis Fischel Outpatient Pharmacy Ellsworth County Health Dept. Elmhurst Hospital Center - Hhc Elmore Co Health Department Elson Student Health Center Elson Student Health Center Erich Pessl, M.D. Erie Co. Home And Infirmary Erie County Dept. of Health Erie County Health Department Erie County Health Dept. Erie County Medical Center Erie County Medical Center Erlanger Medical Center Escambia Co. Public Hlth Dept Escambia County Health Dept Escondido Community Clinic Estill Co Health Dept Etowah Co Health Department

Etowah Qualit of Life Council

Evening Family Planning Clinic

Excelth Network Central City

Excelth, Inc. - Florida/desire

Fagan, Timothy C MD

Fairfax County Health Dept Ph

Fairmont Hospital Pharmacy

Family & Medical Counseling

Family And Medical Counseling

Family Health and Social

Family Health Center

Family Health Center Abo

Family Health Center Pharmacy

Family Health Centers of San Diego

Family Health Network

Family Health of North Ms

Family Health Pharmacy

Family Health Pharmacy

Family Health Pharmacy

Family Health Pharmacy

Family Healthcare Network

Family Hlth Ctr Phcy Inc

Family Med

Family Medical Clinic Phamacy

Family Medical Practice

Family Medicine Pharmacy

Family Pharmacy Inc

Family Planning Council of

Family Practice Pharmacy Abo

Family Practice Pharmacy, Und

Farmacias Plaza #3 (contracted pharmacy)

Farthing, Charles F MD

Fayette County Health Dept

Fayette County Health Dept.

Fenway Community Health Center

Fenway Community Health Center, Inc

Finney County Health Dept.

First Choice Community Health

First Choice Family Health Car

First choice s. Valley clinic

First Choice/Smith's 429

First Choice/Smith's 571 (contracted pharmacy)

Florence Hill Ambulatory Healthcare

Florida Community Health Ctrs

Florida Department of Health

Florida Hlth Sciences Ctr Inc

Foote Hith Center Pharmacy

Foote Hospital Health Center Pharma Forest Manor Adolescent Clinic Forest Manor Comm Health Ctr Forrest General Hospital Forrest General Hospital Homecare/h Forsyth Co. Dept. of Public Health Fort Bend Family Health Center Foster Drug Inc (contracted pharmacy) Franklin C Fetter Family Franklin Co. Health Dept Franklin County Health Department Franklin County Health Dept Franklin County Health Dept. Franklin Health Center Franklin Memorial Hlth Ctr, In Franklin Primary Health Center Franklin Primary(Use Acct#5021 Free Medical Clinic of Fresno County Purchasing Friend Family Health Center Froedtert Clinic Pharmacy Froedtert Hosp Main Opd Phcy Froedtert Hosp/Outpat Phar #1 Fry, Alison Michelle MD Fulton-dekalb Hosp Auth: Grady Infe G A Carmichael Family Hlth Ctr Ga Charmichael Family Hlth Ctr Ga Mountains Community Service Galasso, Philip J MD Gardner Family Health Network Garland Health Center Gasconade County Health Dept. Gaston County Health Department Gateway Community Health Geiger/Gibson Health Ctr Geiger/Gibson Health Ctr Geisert, Cathy Ann MD Genesee Hospital Geneva Co Health Dept. Georgia DW Public Health Georgia Tuberculosis Center Gila Bend Primary Care Gilbert, Cathy Ann MD Gogu, Sudhir R Do Golden Valley Health Center

Gotchel, Richard MD

Grace Hill

Grady Health East Point

Grady IDP Health System

Grady Memorial Hospital

Grady Memorial Hospital

Grady Memorial Hospital

Grady Memorial Outpatient Pharmacy

Grant Co. Health Dept.

Grant County Health Department

Granville-Vance Dist Hlth Dept

Grassy Creek Hlth Center Phcy

Grassy Creek Pharmacy

Great Brook Valley Health Center

Greater Meridan Health Clinic

Greater Meridian Health Clinic

Greater Meridian Health Clinic

Greater New Bedford Community

Green Co Health Department

Greene County Health Dept

Greene County Health Dept

Greene Rural Health Center

Greenup County Health Departme

Greenville Co Health Dept

Greenwood Leflore Hospital

Grundy County Health Dept

Guilford Co Hlth Dept Pharm-wendove

Gulf Coast Health Center

Gurabo Community Health Center

Gwinnett County Health Department

Hackley Pharmacy

Hadden, David M MD

Haines Medical Center

Hale County Health Dept.

Hamilton County Health Dept.

Hamilton County TB Control

Hamlin Pharmacy Inc

Hammond Developmental Center

Hampton Health Department Pharmacy

Hannahville Indian Community

Harbor Health Services Inc

Harbor Health Services Inc.

Harborview Medical Center

Harlem Hospital Center - Hhc Harney County Health Dept. Harris County Hospital District Harrison, Daniel MD Hartford Hospital Hartsville Health Dept Harvard St Neighborhood Hlth Ctr Harvest Family Health Hawaii State Department of Health Heme 4 North Pharmacy Health American Health Care Partners, Inc. Healthnet, Inc Healthnet, Inc Heart of Texas Community Health Cen Helen B Bentley Family Helen Bentley Family Hlth Ctr. Hemophilia Center Henderson County Dept of Public Hea Hennepin Co Med Ctr 4n Phcy Hennepin County Med Center Hennepin County Medical Center Henry Co Health Dept. Henry County Health Department Henry Health Department Herman Keifer Health Complex Hertford County Health Dept Hickory County Health Department Hill Health Center Hillman Health Center Hilltop Health Center Hitawala, Salma MD Hoboken Family Planning, Inc. Hoke County Health Dept Hollywood Sunset Free Clinic Holsten, Ramond L 11 MD Holsten, Raymond L MD Home Infusion Pharmacy Homeless Program

Homer G Phillips Amb Care Center

Hoopa Health Association Hope Medical Center

Horry Co Hlth Dept Std Pr Hospital Pharmacy Hough Norwood Family Hlth Ctr. Houston County Health Dept Howard County Health Dept. Howard County Public HIth Dept Hrs Citrus County Health Dept Hubert H. Humphrey Chc Huron Family Health Center Iberia Medical Center Illinois Department of Public Illinois Dept.of Public Health Indiana Hemophilia And Thrombosis C Indiana University Med Ctr Intercare Community Hlth Net. International District Iowa State Health Department **Ips-West Baltimore Pharmacy** Iredell County Health Department Iron County Health Department Isaac Coggs Health Connection, Inc Island Pond Health Center J.O. Wyatt Community Health Center J.p.s. Health Network (tchd) Jackson - Madison Co Health Departm Jackson County Health Dept Jackson County Health Dept. Jackson County Oregon Hhs Jackson Memorial Hospital Jackson Memorial Hospital Jackson Memorial Medical Center Jackson North Maternity Center Jackson-Hinds, Compr Ctr Janes St Academic Comm Hlth Ctr Jefferson County Health Department Jefferson County Public Health Jefferson Regional Medical Center Jefferson Regional Medical Center Jeffrey Yatsu, M.D. John Hopkins Bayview Med Ctr Johns Hopkins Bayview Johns Hopkins Bayview Medical Cnt Johns Hopkins Hospital Johnson County Public Health Johnson, Pearl D MD Johnston County Public Health Depar

Jones County Health Dept

Joseph M Smith Health Ctr

Kaibeto Health Clinic

Kansas Department of Health

Kansas Dept of Health & Enviro

Kansas State Bureau of Disease

Kansas State Department Health

Karen Nonhof

KDHE-Pharmacy

Kentucky Cabinet For Human Res

Kentucky Cabinet For Human Res

Kern County Health Dept

Kern Medical Center Pharmacy

King, Matthew M MD

Kingman County Health Department

Kings County Health Dept

Kings County Hospital Center - Hhc

Kings County Med Cntr

Kino Community Hospital

Klamath County Health Dept

Knight Drugs CDP #1

Knox County Finance-

Knox County Health Department

Knox County Health Dept

Knox County Health Dept.

Kodiak Public Health Center

La Casa De Buena Salud

La Casa De Buena Salud, Inc

La Casa De Bueno Salud

La Clinica De La Raza

La Clinica De La Raza

La Clinica Del Valle

La Clinica Del Valle Family Health

La Clinica Pediatric Pharmacy

La Clinical Del Valley Family

La Esperanza Clinic

La Maestra Family Clinic

Lac Harbor UCLA Medl Center

Lac Harbor Ucla N-22 Pharmacy

Lac Vieux Desert Band

Lac/usc Medical Center

LAC/USC Medical Center

Laclede County Health Dept

Lafayette County Health Dept

Lagunzad, Edward Payot Do

Lake Powell Medical Center

Lakeview Lynay Pharmacy Lal, Jagdish MD Lamar County Health Department Lancaster County Health Dept Lancaster County Health Dept Lane County Health & Human Services Lauderdale Co. Public Hlth Dpt Laurel Fork Health Commission, Inc. Laurel Heights Clinic Lawndale Christian Hlth Ctr Lawrence Co. Health Dept. Lawrence Douglas County Health Dep Lbj Hospital Lee County Health Department Lehigh Valley Hospital Center Lemuel Shattuck Hospital Lenoir Co Health Dept Lenoir County Health Dept. Leonard J Chabert Med Center Lester, Terry L MD Lewis County Primary Care Ctr Lexington-fay Urba County Lexington-Fayette County Health Dept. Lillian Courtney Health Center Limestone Co. Hlth Dept. Lincoln County H&Hs Department Lincoln County Health Departme Lincoln County Health Dept Lincoln County Health Dept. Lincoln Hospital/Sr Belvis Lincoln Medical & Mental - HHC Linda Vista Hlth Care Ctr Linder, Ryan Lloyd Dds Linn County Dept of Health Linn County Health Dept Lipsitz, Cynthia M MD Lister Hill Health Care Center Little River Medical Center Little Sandy District Health Livingston County Health Ctr Livingston County Health Dept Livingston County Health Dept. Local Hlth Council of East Lopez, Norma I Do Los Angeles Co Dept of Health Svcs Los Angeles Co Dept of Hlth S

Los Angeles Cty Midvalley

Los Angeles Free Clinic

Low Country Health Care

Lowndes Co Public Health Department

Lsu Hospital

Lucile Packard Childrens Hosp

Lummi Indian Health Center

Lummi Phs Indian Hlth Ctr

Lynn Community Health Center

Lynn Community Hlth Ctr, Inc. Schmidtlein, Jill Marie MD

Macon County Health Departmeet

Macon-Bibb County Health Dept

Macphersons Pharmacy

Madison County Health Dept

Madison County Health Dept.

Main Street Health Mary Hall

Malheur County Health Dept

Manatee County Corr Facility

Manatee County Rural Health Service

Manatee County, Rural Health

Manatee County, Rural Health

Marengo Co. Health Department

Maricopa County Correctional Health

Maricopa County Public Health - Cli

Maricopa Medical Center

Maricopa Medical Center

Maricopa Medical Center

Maricopa Medical Center

Marin County Health Department

Marion County Health Dept

Marion County Health Dept.

Mariposa Community Health Cntr

Mariposa Community Health Ctr

Mariposa Community Health Ctr.

Mariposa Pharmacy

Marshall Co Public Health Dept

Marshfield Medical Foundation

Martin Luther King Clinic

Martin Luther King, Jr.

Martin Tyrell Washington Dist

Martin, Barry A MD

Mattapan Community Hlth Ctr

Max C Starkloff Amb Fac Health Ctr

Mayaguez Migrant Hlth Ctr

Mcbride, David R MD

Mcclennan Banks Amb Care Pharm

Mccormick Co Health Dept Mccoy, Beverly J NP Mcg Health, Inc. Mcghi Outpatient Pharmacy Mcormick County Health Dept. MD Dept of Health & Mental Hyg MDPM Hoffman Heights Clinic Meade County Health Department Mecklenburg Co Health Departme Mecklenburg Co Health Dept Med Share Pharmacy Medical Center Medical Center Clinics Medical Center Hospital Employee Ph Medical Center Hospital Pharm Medical Center Hospital Pharmacy Medical Center of Central GA Medical Center of Central GA Medical Center of La Hiv Clnc Medical College of Georgia Medical Ctr of La Nw Orlns/chr Medical University of S Caroli Medical University of SC Memorial Hermann Hospital Memorial Hospital At Gulfport Memphis Health Center, Inc Memphis/shelby Co. Hlth. Dept. Mendocino Coast Health Clinic, Inc. Mendocino Comm Health Clinics Mendocino Comm Hlth Clinic, In Merced Commun Med Ctr Mercer County Health Dept. Mercy Diagnostic & Treatment Mercy Hospital & Medical Cente Merrithew Memorial Outpatient Methodist Specialty/transplant Metro Family Practice Inc Metro Health Dept. of Nashville Metropolitan Hospital Center - Hhc Metropolitan Nashville General Miami County Health Department MIC-Womens Hith Services/MHRA Mid Cumberland Regional Office Migrant Health Program Mile Square Health Center

Mile Square Health Center

Mile Square Neighborhood Clinic

Milwaukee Health Dept Ctrl Ctr

Milwaukee Hlth Services, Inc

Mission Mesa Pediatrics

Mission Neighborhood Health Ct

Mississippi County Health

Mississippi State Department of Hea

Missouri Department of Health

Missouri Department of Health

Missouri Dept of Health

Mitchell County Health Dept.

Mobile County Health Departmen

Mobile County Health Dept

Mohave County Health Departmen

Mohrlock, Richard Dennis Dds

Mon Valley Asn Hlth Ctrs, Inc.

Monroe County Health Dept

Montefiore Medical Group

Montezuma Creek Community

Montgomery Co Health Dept

Montgomery Co Health Dept.

Montgomery County Health & Human

Montgomery County Health Dept

Montgomery County Health Dept

Montgomery Primary Care, HSI

Moore & King Pharmacy - Whitehall B

Moore Co Health Dept

Moore, Douglas L MD

Morgan co. Health department

Morovis Community Health

Morovis Community Health

Morovis Community Hlth.ctr.,inc.

Morovis Community Hlth.Ctr.Inc

Morris Heights Health Center

Morrisania Diagnostic & Treatment C

Morrow County Health Dept

Mortimer, Evan E MD

Mountain Maternal Hlth League

Mountain Park Health Center

Mountain Park Health Center

Mountain People's Health

Mountain Peoples' Hlth Councils,

Mourad, Mohammad Bashshar MD

Mt Auburn Health Center Inc

Mt Shasta Medical Clinic

Mt. Graham Regional Medical Center

Muhlenberg Community Hospital

Multnomah Co. Health Dept.

Musc Hollings Cancer Cente Pharmacy

Musc Mcclennan Banks Pharmacy

Musc Rt Pharmacy

Myrtle Hilliard Davis Comp

N C Baptist Hospital Pharmacy

N Vallley Clinic

Naeem Malik

Naeem, Lubna MD

NAPCH Care Pharmacy (contracted pharmacy)

Naphcare Pharmacy

Naphcare, Inc.

Naranjito Health Center

Naranjito Health Center

Nash County Health Dept

National City Family Clinic

National Jewish Medical & Research

Natividad Medical Center

Natividad Medical Ctr/monterey Co

Navajo County Health Dept

NC Dept of Hlth & Hmn Services

NCBH Piedmont PY

Ncs Healthcare Salisbury

Ne Health Plan

Nebr Hith Sys Summit Plz Phar

Nebraska Health & Human Services

Neighborhood Health Ctr Phcy

Nevada Rural Health Centers-carson

Nevarez, Joseph G MD

New Gouverneur Hospital Snf

New Hanover County Health Departmen

New Hanover County Health Dept

New Haven Clinic

New Horizons Mental Health Clinic,

New York Childrens Health Proj

New York City Dept of Health

New York City Dept. of Health

Newark Beth Isreal Medical Ctr

NJ Dept of Health & Senior Svs

NJ Dept of Health Warehouse

Njl Inc Pharmacy Services

NORCOR

Norfolk Health Department Pharmacy

North Arlington Center

North Arlington Health Center

North Broward Hospital District

North Broward Hospital District

North Campus Pharmacy

North Carolina Baptist Hospital

North Carolina Baptist Hospital

North Carolina Baptist Hospital

North Carolina Baptist Hospitl

North Central Bronx Hospital

North Country Community Health Cent

North County Health Services

North County Health Svcs.

North Dade Health Center

North East Medical Services

North Oakland Medical Center

Northampton County Health Dept

Northeast Health Ctr Pharmacy

Northeast Heatlh Center Pharm

Northeast Medical Group

Northeast Mississippi

Northeast Ohio Neighborhood Health

Northeast Ohio Neighborhood Health

Northeast Valley Health Corp

Northwest Arizona Regional Health C

Northwest Hlth Office

Northwest Medical Ctr Franklin

Northwest Michigan(Use # 4981)

Nw Michigan Comm Health Agcy

NYC Health & Hospital

Nyc Health & Hospital Corp

Oahu Community Mental Health

Oc Public Health Department

Ocean Side Community Hlth Clin

Ocepek, David Brent MD

Oklahoma Department of Health

Oklahoma State Dept of Hlth

Oklahoma State Health Dept

Oldham County Health Dept.

Olive View Med Ctr

Olive View Medical Center

Olson, James J MD

Onslow County Health Dept

Open Door Family Med Center

Oph-dept of Hlth & Human Srvs

Orange County Dept of Health

Orange County Health Department

Oregon County Health Dept

Oregon County Health Dept

Oregon Health Division - Dental Program

Oregon State Health Division

Orocovis Health Center

Osonma, Timothy Ikechukwu MD

Out Patient Pharmacy

Outpatient Pharmacy

Ozark County Health Center

PA Department of Health

PA Dept of Health

Padgett Pharmacy (contracted pharmacy)

Padgett Pharmacy (contracted pharmacy)

Palmetto Richland Memorial Pharmacy

Palmetto Richland Pharmacy, Ps

Park Duvalle Community Health

Park Shore Pharmacy

Park West Medical Center, Inc

Parkland Memorial Hospital

Parkland Memorial Hospital

Parkland Memorial Hospital

Parkland Memorial Hospital

Parks, Steven Neil MD

Parra, Norma G MD

Pasquotank Co Health Dept

Patillas Health Center

Patillas Health Center

Patterson, Janet L MD

Paul Dieringer, M.D.

Pediatric Family Med

Pee Dee Health District

Penn State Milton S. Hershey Medica

Penncare Obgyn At Presbyterian

Penncare Obgyn At Presbyterian

Pennsylvania Dept of Health

Pennsylvania Dept of Health

Penobscot Nation Hlth Dept

People's Family Health Serv.

Peoples Clinic Pharmacy

Peoples Clinic Pharmacy

Peoples Community Health Clinic

Peoples Health Centers Phcy

Perks, Joseph M Do

Perry Co. Health Department

Perry County Health Dept

Person Street Pharmacy of Raleigh Inc

Petaluma Health Care District

Pgpa Pharmacy, Inc

Pharmacy

Pharmerica/henry Welcome Clinic

Phelps County Health Dept

Philadelphia Department of

Philadelphia Department of

Philadelphia Dept of Public

Piedmont Plaza Pharmacy

Piedmont Plaza Pharmacy

Pike Co Health Dept

Pike Community Pharmacy (contracted pharmacy)

Pike Market Med Clinic

Pike Market Medical Clinic

Pikens Co. Health Department

Pima County Health Dept

Pinal County Finance Dept

Pinal County Public Health

Pine Hills Family Health Center

Pioneer Memorial Hospital

PIT River Health Servic, Inc

Pitt County Health Department

Pittsburg Health Center Phcy

Planned Parenthood

Planned Parenthood of

Planned Parenthood of Eastern Oklah

Planned Parenthood of N M

Platte County Health Dept

PMS Pharmacy Services

Polk County Health Dept

Polk County Public Health

Portsmouth Health Department

Portsmouth Health Dept

Potter Valley Community Health Cent

Presbyterian Hospital

Presbyterian Hospital of Greenville

Presbyterian Medical Center

Presbyterian Medical Center

Presbyterian Medical Center

Presbyterian Medical Ctr

Presbyterian Medical Services

Primary Care Center Pharmacy

Primary Care Center Pharmacy

Primary Care Health Services

Primary Health Care Pharmacy

Primary Health Care Services

Primemed Pharmacy Srvcs, Inc

Programa Sida De San Juan Prospect Hill Health Center Providence Community Health Provident Hospital Provident Hospital of Cook County Provident Medical Center Public Health Div, Rx Serv Sect. Pueblo Community Health Center, Putnam County Health Dept Queen's Physicians Office Bldg. Ii Queens Hospital Center Queens Hospital Center - HHC R.o. Watts Medical Ctr Raleigh General Hospital Ralls County Health Department Randolph County Health Dept Rasbury, Pegge Day Do Rea Clinic-christopher Grtr Area Regional Medical Center Regional Medical Center of Memphis Regional Medical Center-Memphi Regional Medical Ctr.At Lubec Regions Hospital Regions Hospital Regions Hospital Pharmacy Renaissance Health Care Ntwk Renaissance Health, diagnostic & Trt Reyes, Miarflor T MD Rice County Health Dept Richard A. Lankes, M. D. Richmond County Health Dept Richmond Health Center Riley County Manhattan Rincon Health Center Rio Grande Comm Health Center Riverside County Regional Medical Riverside Neighborhood Health Riverside San Bernadino Center Roanoke, City Health Dept Pha Robert Mcalister Robeson County Dept of Public Healt Rochester Gen/Gen Apoth Rochester Mental Hlth Ctr. Rochestergeneralhospital Rockingham County Dept of Public He Rockingham County NC

Rodas, Sergio Ulises MD

Roderick Pharmacy Group Inc

Rodriguez-Asbun, Armando MD

Roosevelt Pharmacy

Rosenfeld, Edward J MD

Rossville Health Center

Rowan County Health Dept

Rural Health Care Inc

Rural Health Services, Inc.

Rural Health Svcs Consortium,inc

Russell Ambulatory Ctr Phar

Russell Co Health Dept.

Rutledge Tower Operating Room Pharm

Ryder Memorial Hospital

S C Hou Comm Action Coun

Sacramento County Pharmacy & S

Saliba's Pharmacy (contracted pharmacy)

Saline County Health Departmen

Saline County Health Office

Salt Lake Community Health

Salt Lake Community Health Centers

Salt Lake Community Health Ctr

Sampson County Health Dept

Samuel U. Rodgers Comm. Health Ctr.

Samuel U. Rodgers Comm. Health Ctr.

San Angelo - Tom Green Health Dept.

San Antonio Neighborhood Hlth

San Benito Health Foundation

San Bernardino County of

San Fernando Health Center

San Francisco General Hospital

San Francisco General Hospital

San Joaquin General Hospital

San Joaquin General Hospital O

San Juan Basin Health Department

San Manuel Health Care Center

San Pedro Peninsula Hospital

San Vicente Pharmacy

San Vicente Pharmacy

San Ysidro Health Center

Sanchez, Susan Guzman MD

Santa Barbara Cnty-comm Hlth Clinic

Santa Clara Valley Medical

Santa Clara Valley Medical Center

Sarasota County Health Department

Sarasota County Health Department

Saunders, Stephen E MD

Sc Dhec Marion County Health D

Sc Florence Co Health Dept.

Scenic Bluffs Health Center

Schuyler County Health Dept

Scofield Marques, Sharon S MD

Scotland Co Health Dept

Script Shop Pharmacy

Script Shop Pharmacy

Sea Island Medical Center

Seminole Tribe of Florida

SF General Hospital Med Center

Shah, Syed Nadeem M MD

Shands At Agh

Shands Cancer Center

Shands Hospital

Shands Jacksonville Medical Ct

Shands Medical Plaza

Shands Teaching Hosp & Clinic

Shands Teaching Hosp & Clinic

Shands Teaching Hosp, & Clinic

Shands Teaching Hospital

Shands Teaching Hospital

Shands Teaching Hospital & Clinic

Shands Teaching Hospital And

Shands/Alachua

Shasta Co Health Dept

Shasta Community Health Center

Shawnee County Health

Shelby County Health Dept

Shelby County Health Dept

Siletz Community Hlth Cl Phar

Simenson, Robert D MD

Sinai Community Pharmacy

Sinai Samaritan Medical Center, Inc

Smiths Pharmacy (contracted pharmacy)

Snohomish Health District

Somerton Clinic

Sonoma County Health Services

Sonoma County Indian Health

Sonoma County Indian Health

South Baltimore Family Health

South Baltimore Family Health

South Baltimore Family Hlth, C

South Baltimore Pharmacy

South Bronx Health Center

South Bronx Health Center

South Carolina Department of Health

South Carolina Dhec Std Prog.

South Central Public Health

South County Health Center

South Dakota Dept of Health

South Lake Family Health Ctr

South Lake, Fam Health Center

South Texas Rural Health Servi

Southeast Family Health Care

Southeast Tn Regional Pub Hith

Southern Ohio Health Service

Southern Ohio Health Services

Southside Pharmacy

Southside Pharmacy

Spartanburg Co Health Dept

Spectrum Pharmacy Services

Springfield/Greene County

St Charles County Govt

St Clair Co Health Dept.

St Helena Center

St James-Santee Rural

St Joseph-Buchanan County

St Louis Comprehensive Health

St Paul - Ramsey Co Dept Public Health

St. Claire County Health

St. James Health Center Pharma

St. John Detroit Riverview Hospital

St. Joseph Mercy Care Services

St. Louis Connectcare

St. Louis County D.o.c.h.a.m.c.

St. Mary's Regional Medical Center

St. Vincent Charity Hospital

Stack, Vince John MD

Stadlanders Pharmacy (contracted pharmacy)

Stadtlander Pharmacy (contracted pharmacy)

Stanislaus Outpatient Pharmacy

Stanley Co Health Department

Stanley, Sharilyn K MD

Starceski, Philip Joseph MD

State Lab Institute

State of AL. Clinic Labs

State of Colorado

State of Georgia

State of Hawaii Dept of Health

Statscript #4017

STD Program

Ste Genevieve County Hlt Dept

Stoddard County Health Dept

Stokes County Health Department

Stone Mountain Health Services

Stop Six Community Clinic

Stout Street Clinic

Student Health Service

Suffolk County Dept HIth Svcs.

Suffolk County Dept. of Health Serv

Sullivan County Dept of Health

Sullivan County Health Dept

Sumter Co. Health Dept.

Sun Life Family Health Center

Sun Life Health Center

Suncoast Community Health Center

Sunlife Family Health Care Ctr

Suny - Health Science Ctr At Brookl

Surry County Health & Nutrition Cen

Surry County Health Dept.

Sutter Merced Medical Center

Sutter Merced Medical Center

Swain County Health Dept

Swope Parkway Health Center

Sycuan Medical Dental Center

Syracuse Community Phcy, Inc

Talladega Co Health Department

Talladega Co Health Department

Tallapoosa co. Health dept

Tallapoosa County Health Dept.

Tampa General Hospital

Taney County Health Dept

Tarrant County Hospital District

Tb Control Program

Tegenfeldt, Edwin MD

Tennessee Dept of Health

Texas Dept of Health

The Apothercary At Umgp

The Assistance Fund

The Assistance Fund

The Children's Hospital

The Door Center For Alternativ

The Durham Center

The Genesee Hospital

The Jeffrey Goodman Special

The Ohio Department of Health

The Script Shop, Inc

The Ucsf Ambulatory Care Center

The Winston County Hlth Dept

Thom, Frederick W MD

Thomas E Langley Medical Ctr

Thomas Street Pharmacy

Thompson, Billy N MD

Thunder Bay Comm Hlth - Atlanta

Tiburcio Vasquez Hlth Ctr

Tollesboro Clinic Pharmacy

Tollesboro Clinic Pharmacy

Toren, Carl B MD

Travelers Aid Society

Tri-County Health Dept

Trident Co Health District

Trident Health District

Tulalip Health Clinic

Tulane University Hospital

Tulare Co Health Department

Tuscaloosa Health Department

Uc Davis Cancer Center Pharmacy

Uc Davis Medical Center

Uci Pharmacy Technology

Ucla Medical Center

Ucla Medical Center - Opdcia

UCLA Medical Center Medical

Ucla Medical Plaza

Ucla Medical Plaza - 1st Floor Phar

UCLA Medical Plaza 1st Floor

Ucsd Ambulatory Care Clinic

Ucsd Medical Group Pharmacy

Ulster Co Health Department

Umatilla County Public Health

Umc Quick Care At The Lk Pharm

Und Family Practice Pharmacy

Union Co Health Department

Union County Public Health

United Coalition Pharmacy

United Coalition Pharmacy

United Neighborhood Health Services Cayce Family Health Center

United Neighborhood Health Svcs

Univ Health Network Davis Pharmacy

Univ Health Network Greenwood Pharm

Univ Health Network Mount Ogden Pha

Univ Hospital & Clinics

Univ of Ala Hosp. Clinic/pharmacy

Univ of Arizona

Univ of Calif San Francisco

Univ of California San Diego

Univ of Iowa Hospital & Clnc

Univ of Maryland Hospital

Univ of Maryland Medical Systs

Univ of MD Medical Systems

Univ of Med & Dent of NJ

Univ of Medicine and Dentistry

Univ of Utah Pharmacy At Rocky Mt.

Univ of Virginia Hospital Barringer

Univ of Virginia Med Center

University of Texas Medical Branch

Univerity Hlth Net-Pk City-Phs

University Health Center Dwtn

University Healthcare Center

University Hospital

University Hospital

University Hospital & Clinics

University Hospital & Clinics Pharm

University Hospital of Arkansas

University Hospital, Inc.

University Med Center

University Med Center Home Inf

University Medical Center

University Medical Center OF

University Medical Center of So. NE

University Medical Center, Inc

University of Alabama Hospital

University of Cincinnati Hospital

University of Colorado Hospital

University of Florida Plaza Ph

University of Iowa Hospitals And Cl

University of Kansas

University of Maryland Med Sys

University of Meden & Dntstry of NJ

University of New Mexico Hospital

University of Nm Outpatient Ph

University of Pennsyvania Health

University of Utah

University of Utah

University of Utah Med Center

University of Utah Stansbury Clinic

University of Va Barring

University of VA Medical Center

University of VA Primary Care

University of Virginia Med Ctr

University of Washington

University Physicians Building Phar

Utah Department of Health

Utah State Health Dept

Uvalde County Clinic, Inc.

Vaccination Services of America, In

Valley Aids Council

Valley Health

Valley Health Center At Bascom

Valley Health Center At Chaboya

Valley Health Center At Moorpark

Valley Health Center At Silvercreek

Valley Health Systems Inc

Valley Regional Medical Center

Valley Wide Pharmacy

Vance County Health Dept

Vance-warren Compre, health Plan

Vanderbilt #2 Outpatient

Vanderbilt #2 Outpatient

Vanderbilt University Hosp

Vanderbilt University Medical

Vanderbilt University Medical

Vanderbilt University Medical Cntr

Vanderburgh County Health Dept

Vargas, Efren MD

Ventura County Med Center

Ventura County Medical Center

Ventura County Medical Center

Ventura County Medical Center

Ventura County Ob/Gyn Med Ctr

Vernon County Health Dept

Virginia Beach Health Department

Volusia Chd

Volusia Chd

Vono Pharmacy

Vono Pharmacy

W Al Health Svcs Inc

W VA Department of Health & HU

Wabaunsee County Health Dept

Wabaunsee Health Department

Wahluke Family Health Center Pharma

Wainscott, Barry L MD

Wake County Human Services Pharmacy

Wake Medical Center

Wakulla Medical Center

Walker County Health Dept.

Wallowa County Health Dept

Walton Chd

Warren County Health Dept

Wasco-Sherman Public Health

Washington Co Health Dept

Washington County Public Hlth

Washington Free Clinic

Washington Health Center

Washoe Co Health Dept

Washoe Pharmacy At Ryland

Wateree Public Hlth Dist Phcy

Waverly Belmont Family Health Ct

Wayne County Health Department

Wayne County Medical Clinic

Wells County Health Dept

Wells County Health

West End Pharmacy

West Georgia Health System, Inc.

West Georgia Medical Center

West Oakland Health Council, Inc

West Side Comm Health Services

West Side Community Health Center

West VA Dept-Hlth & Human Res.

Westchester Co.dept.of Health

Westchester County Health Departmen

Westside Community Health

Westside Community Health Cent

Westside Community Hlth Ctr

Westside Health Center

Wewahitchka Medical & Dent Ctr

Whiteside County Health Department

Whitman Walker Clinic

Whitman Walker Clinic, Phcy

CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND KING PHARMACEUTICALS, INC.

I. PREAMBLE

King Pharmaceuticals, Inc., and its United States subsidiaries that manufacture or sell pharmaceutical products (collectively, "King") hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) in which King participates and the requirements of other government programs in which King participates (collectively, "Federal Health Care Programs") specified below in Section II.C.2 (Federal Health Care Program Requirements). Contemporaneously with this CIA, King is entering into a settlement agreement with the United States (Settlement Agreement), and this CIA is incorporated by reference into the Settlement Agreement. King also will enter into settlement agreements with various States, and King's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date of this CIA (as defined below), King established a voluntary compliance program which, as represented by King, includes, among other things, the appointment of a Corporate Compliance Officer, the development and dissemination of a Code of Conduct, the establishment of written policies and procedures, a Disclosure Program, screening measures for Ineligible Persons, review and disciplinary proceedings, regular training to Covered Persons concerning King's Code of Conduct and policies and procedures, and regular internal auditing.

Corporate Integrity Agreement King Pharmaceuticals, Inc.

King shall continue the operation of its compliance measures in accordance with the terms set forth below for the term of this CIA. King may modify its voluntary compliance measures as appropriate, but, at a minimum, King shall ensure that during the term of this CIA, it shall comply with the integrity obligations enumerated in this CIA.

II. TERM AND SCOPE OF THE CIA

- A. The period of the compliance obligations assumed by King under this CIA shall be 5 years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."
- B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) King's final Annual Report; or (2) any additional materials submitted by King pursuant to OIG's request, whichever is later.
 - C. The scope of this CIA shall be governed by the following definitions:
 - 1. "Covered Persons" means:
 - a. all officers, directors, and employees of King based in the United States; and
 - b. except for the Third Party Personnel (as defined below), all contractors, subcontractors, agents, and other persons who perform Government Pricing and Medicaid Drug Rebate Related Functions, as defined below in Section II.C.2, on behalf of King.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

...

King has entered joint venture agreements and agreements to co-market its products with other entities (hereafter "Relevant Third Party Agreements"), including Wyeth Pharmaceuticals (Wyeth). The personnel of the entities with whom King has or may, in the future, have such agreements shall be collectively referred to as "Third Party Personnel." King has represented that: i) the Third Party Personnel are employed by other pharmaceutical manufacturers; ii) King does not control the Third Party Personnel; and iii) it would be unable to compel their compliance with the requirements set forth in this CIA.

For purposes of this CIA, King agrees to promote, to the maximum extent practicable, compliance by the Third Party Personnel with Federal Health Care Program Requirements. In order to fulfill this obligation, King agrees to the following:

- a. within 120 days after the Effective Date and annually thereafter by the anniversary of the Effective Date, King shall send a letter to all entities with which King has entered Relevant Third Party Agreements. The letter shall outline King's obligations under this CIA and its commitment to full compliance with all Federal Health Care Program Requirements. The letter shall include a description of King's compliance program. King shall attach a copy of its Code of Conduct to the letter and ask that the Code of Conduct and the description of King's compliance program be distributed to all relevant Third Party Personnel; and
- b. King shall submit: 1) a copy of each letter (including all attachments); and 2) a list of all King's existing Relevant Third Party Agreements to the OIG with the Implementation Report, the first Annual Report (to the extent the information changes from the date of the Implementation Report) and with each subsequent Annual Report.
- 2. "Relevant Covered Persons" means the following categories of Covered Persons:

1) all employees of King whose job responsibilities relate to the collection, calculation, verification, or reporting of information for purposes of the Medicaid Drug Rebate Program (codified at 42 U.S.C. § 1396r-8, et seq.), the Medicare Program (42 U.S.C. § 1395-1395ggg), or other government programs (including the 340B Drug Pricing Program, codified at 42 USC § 256b (the "340B Program") and the Veterans Administration pricing programs (the "VA Programs"), as set forth in the Federal Supply Schedule and the Veteran's Healthcare Act of 1992) (hereafter collectively, "Government Pricing and Medicaid Drug Rebate Related Functions"). This group includes, but is not limited to, those individuals whose job responsibilities include the calculation and reporting of Average Sales Price, Average Manufacturer Price, Best Price, and all other price information reported and used in connection with reimbursement under the Federal Health Care Programs described in this paragraph; and

2) all contractors, subcontractors, agents, and other persons who perform Government Pricing and Medicaid Drug Rebate Related Functions on behalf of King.

III. CORPORATE INTEGRITY OBLIGATIONS

To the extent not already accomplished, King shall establish and maintain a Compliance Program throughout the term of this CIA that includes the following elements:

A. Corporate Compliance Officer and Committee.

1. Corporate Compliance Officer. King presently has a Corporate Compliance Officer (the "Compliance Officer") with responsibility for administering King's compliance program. King shall continue to employ an individual to serve as its Compliance Officer during the term of this CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed

Corporate Integrity Agreement King Pharmaceuticals, Inc.

to ensure compliance with the requirements set forth in this CIA and with Federal Health Care Program Requirements. The Compliance Officer shall be a member of senior management of King, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Audit Committee of the Board of Directors of King, and shall be authorized to report on such matters to the Audit Committee of the Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by King as well as for any reporting obligations created under this CIA.

King shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. Compliance Committee. Prior to the Effective Date, King established a Compliance Committee (Compliance Committee) and King shall maintain a Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as sales, marketing, government contracting/pricing, regulatory affairs, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

King shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

¹ King has represented that the Audit Committee of the Board of Directors is comprised entirely of independent directors, and that the Compliance Officer makes at least annual reports to the full Board of Directors.

B. Written Standards.

- 1. Code of Conduct. Prior to the Effective Date, King developed, implemented, and distributed a written code of conduct known as the Corporate Code of Conduct and Ethics (the "Code") to all Covered Persons. King shall make the promotion of, and adherence to, the Code an element in evaluating the performance of all employees. The Code shall, at a minimum, set forth:
 - a. King's commitment to full compliance with all Federal Health Care Program Requirements, including its commitment to comply with all government contracting and price reporting requirements, and to market, sell, promote, and advertise its products in accordance with Federal Health Care Program Requirements (including but not limited to, the Federal anti-kickback Statute, codified at 42 U.S.C. § 1320a-7b);
 - b. King's requirement that all of its Covered Persons shall be expected to comply with all Federal Health Care Program Requirements and with King's own Policies and Procedures as implemented pursuant to this Section III.B (including the requirements of this CIA);
 - c. the requirement that all of King's Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by King suspected violations of any Federal Health Care Program Requirements or of King's own Policies and Procedures;
 - d. the possible consequences to both King and Covered Persons of failure to comply with Federal Health Care Program Requirements and with King's own Policies and Procedures and the failure to report such noncompliance; and
 - e. the right of all individuals to use the Disclosure Program described in Section III.E, and King's commitment to nonretaliation

and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, within 120 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by King's Code. New Covered Persons shall receive the Code and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

King shall periodically review the Code to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code within 30 days after the distribution of the revised Code.

- 2. Policies and Procedures. To the extent not already accomplished, within 120 days after the Effective Date, King shall implement written Policies and Procedures regarding the operation of King's compliance program and its compliance with Federal Health Care Program Requirements. At a minimum, the Policies and Procedures shall address:
 - a. the subjects relating to the Code identified in Section III.B.1;
 - b. collecting, calculating, verifying and reporting the data and information reported to the Centers for Medicare & Medicaid Services (CMS), State Medicaid programs or other government entities in connection with Government Pricing and Medicaid Drug Related Functions;
 - c. selling, marketing, and promoting King products in compliance with all applicable Federal Health Care Program Requirements, including, but not limited to, the Federal anti-kickback statute, codified at 42 U.S.C. § 1320a-7b; and

d. disciplinary policies and procedures for violations of King's Policies and Procedures, including policies relating to Federal Health Care Program Requirements.

To the extent not already accomplished, within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed in hard-copy or electronic format to all individuals whose job functions relate to those Policies and Procedures. Distribution may include publishing such Policies and Procedures on King's intranet or a web site, including the Axentis Corporate Governance System. If King publishes such Policies and Procedures on its intranet or a web site, King must notify the relevant persons receiving such Policies and Procedures that the Policies and Procedures will be distributed in such a manner and King must track distribution to ensure that all appropriate relevant persons received the Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), King shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

- 1. General Training. Within 120 days after the Effective Date, King shall provide at least two hours of General Training to each Covered Person². This training, at a minimum, shall explain King's:
 - a. CIA requirements;
 - b. Compliance Program (including the Code and the Policies and Procedures as they pertain to general compliance issues); and

² Independent directors of King shall receive training on the topics set forth in Sections III.C.1.a-b of the CIA. King has represented that its independent directors sit on King's Board of Directors and are not members of King's management.

c. in general, in a manner appropriate for the individual's job function, the proper methods of promoting, marketing and selling, and contracting for products in accordance with Federal Health Care Program Requirements; the need to calculate and report accurate pricing and other information in connection with the Government Pricing and Medicaid Drug Rebate Related Functions; and a general discussion of King's systems relating to the Government Pricing and Medicaid Drug Rebate Related Functions.

New Covered Persons shall receive the General Training described above within 45 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training annually.

- 2. Specific Training. Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least two hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:
 - a. in detail, and as appropriate for the individual's job functions, King's systems for gathering relevant data and calculating, verifying, and reporting information to CMS and/or the State Medicaid Programs for purposes of the Medicaid Drug Rebate Program, the Medicare Program, the 340B Program or the VA Programs;
 - b. all applicable Federal Health Care Program Requirements (including the sanctions for violations) relating to Government Pricing and Medicaid Drug Rebate Related Functions;
 - c. the personal obligation of each individual to comply with Federal Health Care Program Requirements, and, as appropriate for the individual's job functions, applicable legal requirements referenced above in Section III.C.2.b. and to track and review any pricing or

contract exceptions, variations, or outliers identified within King's systems;

- d. the legal sanctions for violations of the Federal Health Care Program Requirements referenced above in Section III.C.2.b; and
- e. examples of proper and improper practices related to Government Pricing and Medicaid Drug Rebate Related Functions.

Relevant Covered Persons shall receive this training within 45 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. A King employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to Government Pricing and Medicaid Drug Rebate Related Functions, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least two hours of Specific Training annually.

- 3. Certification. Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.
- 4. Qualifications of Trainer. The training and education required under this Section III.C may be provided by supervisory employees, knowledgeable staff, King trainers, and/or outside consultant trainers selected by King. The Specific Training requirements outlined in Section III.C.2 may be satisfied through relevant continuing education programs offered by established and knowledgeable providers, so long as the programs cover the topics outlined in Section III.C.2. Persons providing the training shall be knowledgeable about the applicable subject areas, including the relevant Federal Health Care Program Requirements relating to the promotion, sales, and marketing of

King's products and requirements applicable to Government Pricing and Medicaid Drug Rebate Related Functions.

- 5. Update of Training. King shall annually review the training, and, where appropriate, update the training to reflect changes in applicable Federal Health Care Program Requirements, any issues discovered during internal audits or the IRO Reviews, and any other relevant information.
- 6. Computer-based Training. King may provide the training required under this CIA through appropriate computer-based training approaches. In that event, all applicable references to "hours" in this Section III.C shall mean "normative hours" as that term is used in the computer-based training industry. If King chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.
- 7. Miscellaneous Training Related Provisions. To the extent that King has provided training that satisfies the General or Specific Training requirements set forth above within 180 days prior to the Effective Date, the OIG shall credit that training for purposes of satisfying King's training obligations for the first Reporting Period of the CIA. For purposes of the General Training requirements, if King provided General Training that satisfies the requirements set forth in Section III.C.1 above to Covered Persons within 180 days prior to the Effective Date, King may satisfy its remaining General Training obligation for the first year of the CIA by notifying those Covered Persons of the fact that King entered a CIA and notifying them of King's requirements and obligations under the CIA.

King provides training on a regular basis concerning a variety of topics to its employees. The training required by this CIA need not be separate and distinct from the regular training provided by King, but instead may be integrated fully into such regular training to the extent the training satisfies the requirements set forth in this CIA.

To the extent a Covered Person is on a leave of absence when the required training is offered, the Covered Person shall receive the training within 30 days of the conclusion of the leave of absence.

D. Review Procedures.

1. General Description.

a. Engagement of Independent Review Organization. Within 120 days after the Effective Date, King shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter the "Independent Review Organization" or "IRO"), to perform reviews to assist King in assessing and evaluating its systems, processes, policies, and practices related to the Government Pricing and Medicaid Drug Rebate Related Functions. The applicable requirements relating to the IRO are outlined in Appendix A to this Agreement, which is incorporated by reference.

Each IRO engaged by King shall have expertise in the applicable Federal Health Care Program Requirements and other applicable legal requirements, as may be appropriate to the Engagement for which it is retained. Each IRO shall assess, along with King, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist.

The IRO(s) review shall evaluate and analyze King's systems, processes, policies, and practices relating to the Government Pricing and Medicaid Drug Rebate Related Functions (the "Government Pricing and Medicaid Drug Rebate Engagement" or the "Engagement").

- b. Frequency of Engagement. The Government Pricing and Medicaid Drug Rebate Engagement shall be performed annually and shall cover each of the Reporting Periods.
- c. Retention of Records. The IRO and King shall retain and make available to OIG, upon request, (i) all work papers relating to the

Engagement, and (ii) all supporting documentation, correspondence, and draft reports (those exchanged between the IRO and King) related to the Engagement.

- d. Entity Performing Engagements. The Engagements shall each be performed by the IRO, as specified in this Section III.D and the Appendices to this CIA, during the five Reporting Periods of the CIA. However, after the IRO(s) performs the first three Government Pricing and Medicaid Drug Rebate Engagements, King, at its option, may request the OIG to permit that those Engagements be conducted internally and subject only to verification by the IRO for the remainder of the term of the CIA. The OIG retains sole discretion over whether to permit those Engagements to be conducted internally by King and subject to validation by the IRO. In making its decision, the OIG will consider, among the factors, the results of the Engagements during the first three Reporting Periods of the CIA and King's demonstrated audit capabilities to perform the Engagements internally. If the OIG denies King's request to shift the audit responsibilities, King agrees to engage the IRO to complete the remaining Engagements in accordance with the CIA.
- 2. Government Pricing and Medicaid Drug Rebate Engagement. As set forth more fully in Appendix B and below, the Government Pricing and Medicaid Drug Rebate Engagement shall consist of two components a Systems Review and a Transactions Review. If there are no material changes in King's Government Pricing and Medicaid Drug Rebate related systems, processes, policies, and practices during the term of the CIA, the IRO shall perform the Government Pricing and Medicaid Drug Rebate Engagement Systems Review covering the second and fourth Reporting Periods. If King materially changes its systems, processes, policies and practices relating to government pricing or the Medicaid Drug Rebate Program, then the IRO shall perform a Government Pricing and Medicaid Drug Rebate Engagement for the Reporting Period in which such changes were made in addition to conducting the Medicaid Drug Rebate Engagement for the second and fourth Reporting Periods. The Transactions Review shall be performed annually and shall cover each of the five Reporting Periods.

- 3. Government Pricing and Medicaid Drug Rebate Engagement Report.

 The IRO shall prepare a report based upon the Engagement performed (Engagement Report). Information to be included in the Engagement Report is described in Appendix B.
- 4. <u>Validation Review</u>. In the event OIG has reason to believe that: (a) King's Engagement fails to conform to the requirements of this CIA; or (b) the IRO's findings or Engagement results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Engagement complied with the requirements of this CIA and/or the findings or Engagement results are inaccurate (Validation Review). King shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of King's final Annual Report must be initiated no later than one year after King's final submission (as described in Section II.B) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify King of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, King may request a meeting with OIG to: (a) discuss the results of any Engagement submissions or findings; (b) present any additional information to clarify the results of the Engagement or to correct the inaccuracy of the Engagement; and/or (c) propose alternatives to the proposed Validation Review. King agrees to provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Engagement issues with King prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

5. Independence/Objectivity Certification. The IRO shall include in its report(s) to King a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the Engagement, with regard to the Engagement and that it has concluded that it is, in fact, independent and/or objective.

E. <u>Disclosure Program.</u>

Prior to the Effective Date, King established a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with King's policies, conduct, practices, or procedures with respect to a Federal Health Care Program Requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. King shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas), and King shall maintain the Disclosure Program during the term of the CIA.

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure that relates to a Federal Health Care Program Requirement, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the inappropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, King shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received that relates to a Federal Health Care Program Requirement (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG upon request.

F. Ineligible Persons.

- 1. Definitions. For purposes of this CIA:
 - a. an "Ineligible Person" shall include an individual or entity who:
 - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal Health Care Programs or in Federal procurement or nonprocurement programs; or
 - ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
 - b. "Exclusion Lists" include:
 - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov); and
 - ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov).
 - c. "Screened Persons" means prospective and current owners (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading), officers, directors, employees, contractors, and agents of King.
- 2. Screening Requirements. King shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements:
 - a. King shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or

contracting process, shall require such persons to disclose whether they are an Ineligible Person.

- b. King shall screen all Screened Persons against the Exclusion Lists within 120 days after the Effective Date and on an annual basis thereafter.
- c. King shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

To the extent that King has screened certain Screened Persons against the Exclusions Lists and required disclosure of eligibility status within 180 days prior the Effective Date, such actions will satisfy King's obligations with regard to those Screened Persons for purposes of Section III.F.2.b for the first year of the CIA.

- 3. Removal Requirement. If King has actual notice that a Screened Person has become an Ineligible Person, King shall remove such person from responsibility for, or involvement with, King's business operations related to the Federal Health Care programs and, if applicable, shall remove such person from any position for which the person's compensation or the items or services furnished, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal Health Care Programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.
- 4. Pending Charges and Proposed Exclusions. If King has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during his or her employment or contract term, King shall take all appropriate actions to ensure that the responsibilities of that person have not and shall not affect the accuracy of any claims submitted to any Federal Health Care Program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery by senior management at King's corporate headquarters, King shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to King conducted or brought by a governmental entity or its agents involving an allegation that King has committed a crime or has engaged in fraudulent activities in the United States (including the United States, the District of Columbia, and the territories and possessions of the United States). This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. King shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

H. Reportable Events.

- a. <u>Definition of Reportable Events</u>. For purposes of this CIA, a "Reportable Event" means anything that involves a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal Health Care Program for which penalties or exclusion may be authorized. A Reportable Event may be the result of an isolated event or a series of occurrences.
- b. Notification of Reportable Events. If King determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, King shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:
 - i. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal Health Care Program authorities implicated;

ii. a description of King's actions taken to correct the Reportable Event; and

iii. any further steps King plans to take to address the Reportable Event and prevent it from recurring.

King's notification of OIG of any Reportable Event pursuant to this CIA does not preclude King from making the same disclosure through OIG's Self-Disclosure Protocol.

IV. New Business Units or Locations

In the event that, after the Effective Date, King changes locations or sells, closes, purchases, or establishes a new business unit or other location engaged in Government. Pricing and Medicaid Drug Rebate Related Functions or in the promotion, sales, or marketing of items that may be reimbursed by Federal Health Care Programs (collectively "Relevant Activities"), King shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or other location, phone number, fax number, Federal Health Care Program provider or supplier number (if any), and the corresponding contractor's name and address that has issued each provider or supplier number. Each new business unit or location that is engaged in the Relevant Activities shall be subject to all the requirements of this CIA.

King shall use its best efforts to implement the requirements of this CIA in new business units or other locations engaged in Relevant Activities. Notwithstanding any other provisions to the contrary, the requirements of this CIA shall not become effective for new business units or other locations until 120 days after the purchase or establishment or acquisition of such new business units or locations.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. <u>Implementation Report</u>. Within 120 days after the Effective Date, King shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

- 1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
- 2. the names and positions of the members of the Compliance Committee required by Section III.A;
 - 3. a copy of King's Code required by Section III.B.1;
 - 4. a copy of all Policies and Procedures required by Section III.B.2;
- 5. the number of individuals required to complete the Code certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
- 6. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;
 and
 - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials used in the training required by Section III.C and the documentation supporting this information shall be available to OIG, upon request.

- 7. a description of the Disclosure Program required by Section III.E;
- 8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between King and the IRO; and (d) the proposed start and completion dates of the Engagement;

- 9. a certification from the IRO regarding its professional independence and/or objectivity with respect to King;
- 10. a description of the process by which King fulfills the requirements of Section III.F regarding Ineligible Persons;
- 11. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F; and the actions taken to identify, quantify, and repay any overpayments to Federal Health Care Programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;
- 12. a list of all of King's locations (including locations and mailing addresses) as required by Section IV; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal Health Care Program provider or supplier number(s) (if any); and the name and address of each contractor to which King currently submits claims (if any);
- 13. a description of King's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business;
 - 14. the certifications required by Section V.C, and
- 15. a list of all King's existing Relevant Third Party Agreements, as required by Section II.C.1.
- B. <u>Annual Reports</u>. King shall submit to OIG annually a report with respect to the status of, and findings regarding, King's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

- 1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;
- 2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (<u>e.g.</u>, change in contractor policy) and copies of any such Policies and Procedures that have changed since previously provided to the OIG;
- 3. the number of individuals required to complete the Code certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
- 4. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions; and
 - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

- 5. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);
- 6. King's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;

- 7. a summary and description of any and all current and prior engagements and agreements between King and the IRO, if different from what was submitted as part of the Implementation Report;
- 8. a certification from the IRO regarding its professional independence and/or objectivity with respect to King;
- 9. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;
- 10. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal Health Care Program Requirements;
- 11. any changes to the process by which King fulfills the requirements of Section III.F regarding Ineligible Persons;
- 12. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken by King in response to the screening and removal obligations set forth in Section III.F; and the actions taken to identify, quantify, and repay any overpayments to Federal Health Care Programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;
- 13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
- 14. a description of all changes to the most recently provided list of King's locations (including addresses) as required by Section V.A.12; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal Health Care Program provider or supplier number(s) (if any); and the name and address of each Federal Health Care Program contractor to which King currently submits claims (if any);

- 15. the certifications required by Section V.C; and
- 16. a list of all King's existing Relevant Third Party Agreements, as required by Section II.C.1.

The first Annual Report shall be received by OIG no later than 90 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

- C. <u>Certifications</u>. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that:
- 1. except as expressly provided in the certification relating to policies and materials under development or subject to revision, all policies and procedures, standardized contracts, promotional materials, and training materials relating to Government Pricing and Medicaid Drug Rebate Related Functions and to the promotion, sales, or marketing of King's products have been reviewed by legal counsel and been found to be in compliance with all applicable Federal Health Care Program Requirements;
- 2. King has provided to the OIG the Medicaid Drug Rebate certification as set forth in Appendix C covering the applicable Reporting Period(s), and such certification is true and correct in all respects;
- 3. to the best of his or her knowledge, except as otherwise described in the applicable report, King is in compliance with all of the requirements of this CIA;
- 4. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful; and
- 5. if applicable, King has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise

seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs.

D. <u>Designation of Information</u>. King shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. King shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: (202) 619-2078
Facsimile: (202) 205-0604

King:

Frederick Brouillette, Jr. King Pharmaceuticals, Inc. Corporate Compliance Officer 501 Fifth Street Bristol, TN 37620

Telephone: (423) 989-8751 Facsimile: (423) 274-8612

with a copy to:

General Counsel King Pharmaceuticals, Inc. 501 Fifth Street Bristol, TN 37620 Telephone: (423) 989-8000 Facsimile: (423) 990-2566

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of King's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of King's locations for the purpose of verifying and evaluating: (a) King's compliance with the terms of this CIA; and (b) King's compliance with the requirements of the Federal Health Care Programs. The documentation described above shall be made available by King to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of King's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. King shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. King's employees may elect to be interviewed with or without a representative of King present.

VIII. DOCUMENT AND RECORD RETENTION

King shall maintain for inspection all documents and records relating to reimbursement from the Federal Health Care Programs, or to compliance with this CIA, for six years from the Effective Date (or longer if otherwise required by law).

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify King prior to any release by OIG of information submitted by King pursuant to its obligations under this CIA and identified upon submission by King as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, King shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. Breach and Default Provisions

A breach of this CIA does not constitute a breach of the Settlement Agreement between King and the United States or the settlement agreements with the individual States referred to in the Preamble to this CIA. Any breach of the terms of those agreements does not constitute a breach of the CIA, except to the extent that such a breach independently also constitutes a breach of this CIA. This Section X specifies all of the remedies available to the OIG if King fails to satisfy its obligations under this CIA. The remedies available to the OIG under this Section X do not preempt or limit any actions that individual States may take against King under the appropriate authorities not specified in this CIA.

King is expected to fully and timely comply with all of its CIA obligations.

A. <u>Stipulated Penalties for Failure to Comply with Certain Obligations</u>. As a contractual remedy, King and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

- 1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day King fails to establish and implement any of the following obligations as described in Section III:
 - a. a Compliance Officer;
 - b. a Compliance Committee;
 - c. a written Code of Conduct;
 - d. written Policies and Procedures;
 - e. the training of Covered Persons;
 - f. a Disclosure Program;
 - g. Ineligible Persons screening and removal requirements; and
 - h. Notification of Government investigations or legal proceedings.
- 2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day King fails to engage an IRO, as required in Section III.D and Appendix A.
- 3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day King fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.
- 4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day King fails to submit the annual Engagement Report in accordance with the requirements of Section III.D and Appendix B.
 - 5. A Stipulated Penalty of \$1,500 for each day King fails to grant access to

the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date King fails to grant access.)

- 6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of King as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.
- 7. A Stipulated Penalty of \$1,000 for each day King fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to King, stating the specific grounds for its determination that King has failed to comply fully and adequately with the CIA obligation(s) at issue and the steps King shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after King receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.
- B. Timely Written Requests for Extensions. King may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after King fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after King receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. Demand Letter. Upon a finding that King has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify King of: (a) King's failure to comply; and (b) OIG's

exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter"). Such demand letter shall state the conduct that the OIG contends constitutes the basis for imposing the Stipulated Penalty.

- 2. Response to Demand Letter. Within 10 days after the receipt of the Demand Letter, King shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event King elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until King cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.
- 3. Form of Payment. Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.
- 4. Independence from Material Breach Determination. Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that King has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

- 1. Definition of Material Breach. A material breach of this CIA means:
 - a. a failure by King to report a Reportable Event and take corrective action, as required in Section III.H;
 - b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.D.
- 2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this CIA by King constitutes an independent basis for King's exclusion from participation in the Federal health care programs. Upon a determination by OIG that King has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify King of: (a) King's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").
- 3. Opportunity to Cure. King shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:
 - a. King is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
 - b. the alleged material breach has been cured; or
 - c. the alleged material breach cannot be cured within the 30-day period, but that: (i) King has begun to take action to cure the material breach; (ii) King is pursuing such action with due diligence; and (iii) King has provided to OIG a reasonable timetable for curing the material breach.
- 4. Exclusion Letter. If, at the conclusion of the 30-day period, King fails to satisfy the requirements of Section X.D.3, OIG may exclude King from participation in the Federal health care programs. OIG shall notify King in writing of its determination to exclude King (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of King's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and

nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, King may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

- 1. Review Rights. Upon OIG's delivery to King of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, King shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.
- 2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether King was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. King shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders King to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless King requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.
 - 3. Exclusion Review. Notwithstanding any provision of Title 42 of the

United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether King was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) King had begun to take action to cure the material breach within that period; (ii) King has pursued and is pursuing such action with due diligence; and (iii) King provided to OIG within that period a reasonable timetable for curing the material breach and King has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for King, only after a DAB decision in favor of OIG. King's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude King upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that King may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. King shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of King, King shall be reinstated effective on the date of the original exclusion.

4. Finality of Decision. The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. <u>Effective and Binding Agreement</u>

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, King and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of King;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;
- D. The undersigned King signatories' represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA; and
- E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement.

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KING PHARMACBUTICALS

2002

ON BEHALF OF KING PHARMACEUTICALS, INC.

Frederick Brouillette, Jr. Corporate Compliance Officer DATE

Marc S. Rosenberg, Esq.

Counsel for King Pharmaceuticals, Inc.

TS A 1793

Lewis Morris

Chief Counsel to the Inspector General

Office of Inspector General
U. S. Department of Health and Human Services

Corporate Integrity Agreement

King Pharmaceuticals, Inc.

APPENDIX A INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA. Capitalized terms used in this Appendix A and not defined herein have the meanings assigned to them in the CIA.

A. <u>IRO Engagement</u>.

King shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and/or objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify King if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, King may continue to engage the IRO.

If King engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix A. If a new IRO is engaged, King shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify King if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, King may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

- 1. assign individuals to conduct the Government Pricing and Medicaid Drug Rebate Engagement who have expertise in the Federal Health Care Program Requirements;
- 2. assign individuals who are knowledgeable about the appropriate statistical sampling techniques and select the samples required for the Government Pricing and Medicaid Drug Rebate Engagement; and
- 3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. <u>IRO Responsibilities</u>.

The IRO shall:

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- 1. perform each Government Pricing and Medicaid Drug Rebate Engagement in accordance with the specific requirements of the CIA;
- 2. follow all applicable Federal Health Care Program Requirements in making assessments in the Government Pricing and Medicaid Drug Rebate Engagement;
- 3. request clarification from the appropriate authority (e.g., CMS), if in doubt as to the application of a particular Medicare or Medicaid Drug Rebate Program policy or regulation that is not addressed in King's Policies and Procedures;
 - 4. respond to all OIG inquires in a prompt, objective, and factual manner; and
- 5. prepare timely, clear, well-written reports that include all the information required by Appendix B.

D. <u>IRO Independence/Objectivity</u>.

The IRO must perform the Government Pricing and Medicaid Drug Rebate Engagement in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and King.

E. <u>IRO Removal/Termination</u>.

- 1. Provider. If King terminates its IRO during the course of the engagement, King must submit a notice explaining its reasons to OIG no later than 30 days after termination. King must engage a new IRO in accordance with Paragraph A of this Appendix A.
- 2. OIG Removal of IRO. In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B of this Appendix A, is not independent and/or objective as set forth in Paragraph D of this Appendix A, or has failed to carry out its responsibilities as described in Paragraph C of this Appendix A, OIG may, at its sole discretion, require King to engage a new IRO in accordance with Paragraph A of this Appendix A.

Prior to requiring King to engage a new IRO, OIG shall notify King of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, King may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. King shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO

Appendix A King Pharmaceuticals CIA Page 2 with King prior to requiring King to terminate the IRO. However, the final determination as to whether or not to require King to engage a new IRO shall be made at the sole discretion of OIG.

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Appendix B to the CIA for King Pharmaceuticals, Inc. Government Pricing and Medicaid Drug Rebate Engagement

This Appendix B contains the requirements relating to the Engagement required to be performed by the Independent Review Organization under Section III.D of the CIA. Capitalized terms used herein and not defined herein have the meanings assigned to them in the CIA.

I. Government Pricing and Medicaid Drug Rebate Engagement - General Descriptions

As specified more fully below, King Pharmaceuticals, Inc. (King), shall retain an Independent Review Organization (IRO) to perform reviews to assist King in assessing and evaluating its systems, processes, policies, and practices (including the controls on the systems, processes, policies, and practices) related to its government price reporting requirements for Best Price (BP) and Average Manufacturer Price (AMP) under the Medicaid Drug Rebate Program and for Average Sales Price (ASP) for purposes of the Medicare program. The IRO shall perform two types of engagements: 1) a systems review of King's systems, processes, policies, and practices relating to the calculation and reporting of AMP, BP and ASP (collectively "Systems Review Consulting Engagement"); and 2) testing of samples of transactions to assess whether King is calculating AMP and BP in accordance with the policies, procedures, and methodologies developed by King relating to the Medicaid Drug Rebate Program (Medicaid Drug Rebate Transactions Engagement).

Prior to performing the Government Pricing and Medicaid Drug Rebate Engagement, the IRO and King shall design Consulting Procedures outlining the specific work to be performed by the IRO, and the Consulting Procedures may be submitted to the OIG for comment. However, any comments or recommendations made by the OIG in connection with a review of the submitted workplan(s) will not preclude the OIG from making further comments or recommendations for future workplan(s) after reviewing the reports from the Government Pricing and Medicaid Drug Rebate Engagement.

If there are no material changes in King's systems, processes, policies, and practices during the term of the CIA, then the IRO shall perform the Systems Review Consulting Engagement covering the second and fourth Reporting Periods. If King materially changes its systems, processes, policies, and practices as they relate to the calculation of AMP, BP, or ASP, then the IRO shall perform a Systems Review Consulting Engagement

covering the Reporting Period in which such changes were made in addition to conducting the Engagement for the second and fourth Reporting Periods. The additional Systems Review Consulting Engagement(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether the systems, processes, policies, and practices already reported on did not materially change; and 3) an update on the systems, processes, policies, and practices that materially changed.

The Medicaid Drug Rebate Transactions Engagement shall be designed to test whether King is calculating AMP and BP in accordance with the policies, procedures, and methodologies developed by King relating to the Medicaid Drug Rebate Program. The Medicaid Drug Rebate Transaction Engagement shall consist of two parts, the "Reported Prices Procedures for AMP," and the "Reported Prices Procedures for BP."

Consistent with Section III.D.1.d of the CIA, after the third Reporting Period, the OIG may, at its discretion and upon written request of King, permit King to perform the engagements described in this Appendix B, subject to verification by the IRO.

II. Systems Review Consulting Engagement

A. Average Sale Price Systems Review

For at least the second and fourth Reporting Periods, the IRO shall review King's systems, processes, policies, and practices (including the controls on the systems, processes, policies, and practices) associated with the tracking, gathering, verifying, and accounting for all relevant data for purposes of calculating ASP reported to the Centers for Medicare and Medicaid Services (CMS) as required under the Medicare program.

In general terms, the IRO shall review the following:

- 1. the systems, processes, policies, and practices in place to track, gather, and appropriately account for price terms and transactions with King customers that are relevant for purposes of the ASP calculation and reporting requirements. Specifically, this includes:
 - a) the process, policies, and procedures used to determine which customers are included in the calculation of ASP for ASP covered products;

- b) the process, policies, and procedures used to determine whether and which particular transactions reflecting final sales prices are included in or excluded from the ASP calculation;
- a review of King's methodology for applying transactions to the ASP calculations;
- d) the relevant flow of data and information by which price terms and transactions with King customers are accumulated from source systems and entered and tracked in King's ASP system for purposes of calculating ASP;
- e) a review of any King inquiries to CMS regarding the ASP calculation and reporting requirements and any responses to those inquiries; and
- f) the controls and processes in place to examine and address system reports that require critical evaluation (such as reports of variations, exceptions, and outliers). This shall include a review of the basis upon which variations, exceptions, and outliers are identified and the follow-up activities undertaken to identify the cause of any variations.

B. <u>Medicaid Rebate Systems Review</u>

For at least the second and fourth Reporting Periods, the IRO shall review King's systems, processes, policies, and practices (including the controls on the systems, processes, policies, and practices) associated with the tracking, gathering, and accounting for all relevant data for purposes of calculating and reporting AMP and BP to CMS under the Medicaid Drug Rebate Program.

In general terms, the IRO shall review the following:

- 1. The systems, processes, policies, and practices that are in place to track, gather, and appropriately account for contract terms and transactions with King customers that are relevant to the calculation of AMP and BP under Medicaid Drug Rebate Program. Specifically, this includes a review of:
 - a) the process used to determine which customers are

included in the calculation of AMP and BP for Medicaid rebate eligible products;

- b) the process used to determine whether and which discounts or rebates in King customer contracts, or other price terms or transactions with King customers, are included in the calculation of BP and AMP for Medicaid rebate eligible products;
- c) a review of the methodology for applying transactions to the AMP and BP calculations;
- d) the relevant flow of data and information by which price terms and transactions with King customers are accumulated from the source systems and entered and tracked in King's information systems for purposes of calculating the AMP and BP;
- e) a review of any King inquiries to CMS regarding the Medicaid Drug Rebate Program (including those pertaining to the determination of AMP and BP) and any responses to those inquiries; and
- f) the controls and processes in place to examine and address system reports that require critical evaluation (such as reports of variations, exceptions, and outliers). This shall include a review of the basis upon which variations, exceptions, and outliers are identified and the follow-up activities undertaken to identify the cause of any variations.

C. Systems Review Consulting Engagement Report

For each relevant Reporting Period, the IRO shall prepare a report based upon the Systems Review Consulting Engagement. This report may be combined with the report for the Medicaid Drug Rebate Transactions Engagement and shall include the following:

1. A description of the systems, processes, policies, and practices in place to track, gather, and account for price terms, contract terms, and transactions with King customers that are relevant to the calculation and reporting of AMP, BP, and ASP including, but not limited to:

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- a) the computer or other relevant systems (including the source systems, and any other information systems (as applicable) used to calculate and report AMP, BP, and ASP;
- b) the information input into King's relevant computer or other systems used to calculate AMP, BP, and ASP;
- c) the system logic or decisional rationale used to determine which King customers are included for purposes of calculating AMP, BP, and ASP;
- d) the system logic or decisional rationale used to determine whether contract terms, discounts, rebates and all other relevant transactions with King customers are included or excluded when calculating AMP, BP and ASP; and
- e) the policies and practices of the Government Contracts and Commercial Contracts subgroups of King's Contract Administration Group in examining system reports for variations that require critical evaluation, including the bases upon which variations, exceptions, and outliers are identified, and the follow up actions taken in response.
- 2. A description of the documentation, information, and systems reviewed and the personnel interviewed, if any, including a description of the following:
 - a) King's inquiries to CMS regarding the Medicaid Drug Rebate Program or the Medicare Program (including those pertaining to the determination of AMP, BP, and ASP) and any responses to those inquiries;
 - b) King's systems and practices for reporting AMP, BP, and ASP to CMS for purposes of the Medicaid Drug Rebate Program on a quarterly basis; and
 - c) King's systems and practices for making any adjustments to reported AMP, BP, or ASP or additional information related to the submissions.

3. Observations, findings, and recommendations on possible improvements to King's systems, processes, policies, and practices.

III. Medicaid Drug Rebate Transactions Engagement

Except for the first Reporting Period as provided below, following the end of each Reporting Period, the IRO shall randomly select one quarter for review in the Medicaid Drug Rebate Transactions Engagement, including both the BP and AMP procedures described in this Section III. For the first Reporting Period, the selected quarter shall be one in which King's new system for performing Medicare and Medicaid calculations was installed and in use.

A. Reported Prices Procedures for BP

For each Reporting Period, the IRO shall conduct Reported Prices Procedures for BP to test whether King calculated and reported BP in accordance with King' policies and procedures and methodology developed for the Medicaid Drug Rebate Program.

The Reported Prices Procedures for BP shall consist of two parts:

Part One of Reported Prices and Procedures for BP

The IRO will obtain a listing of all King Customers¹ to whom sales of Medicaid rebate eligible products were made at contracted prices during the selected quarter of the Review Period. The IRO will randomly select a sample of 20 King Customers using the following methodology. The IRO will aggregate the number of NDCs² for each King Customer and will categorize each King Customer as "large" or "small" based upon the total volume of sales³ of the contracted Medicaid rebate eligible NDCs to that King Customer in the Reporting Period quarter selected. The IRO shall randomly

A King Customer is any commercial (a) customer with whom King contracts directly for the sale of pharmaceutical products at discounted prices and (b) managed care entity to which King pays rebates based on the utilization of its pharmaceutical products by covered persons.

² For purposes of this Appendix B, "NDC" means a single dosage, form, and strength of a pharmaceutical product, without regard to package size (i.e., an NDC 9).

For purposes of this Section III, "volume of sales" means: (i) with respect to purchasers of King's pharmaceutical products, net sales before government rebates; and (ii) for managed care entities, utilization (equal to WAC less unit rebate amount), in either case, in the most recent quarter for which complete data is available.

select 10 King Customers from the large King Customer pool and 10 King Customers from the small King Customer pool.

The IRO's review shall cover the five NDCs for which King paid the largest amount (i.e., total dollars) of Medicaid rebates for the Reporting Period and five randomly selected NDCs (collectively, the "Selected BP NDCs"); provided that if King paid less than \$20,000 in Medicaid rebates for the Reporting Period for any randomly selected NDC, the IRO will replace such NDC with a randomly selected NDC for which King paid at least \$20,000 in Medicaid rebates for the Reporting Period.

For each King Customer selected, the IRO will identify all contracts with King and all Selected BP NDCs for which the King Customer had a contract price with King. The IRO will then test for each King Customer selected that each contract price for each Selected BP NDC is accurately reflected in King's government pricing system(s) and that the contract price is appropriately considered for purposes of determining BP in accordance with the policies, procedures, and methodology developed by King relating to the Medicaid Drug Rebate Program. To the extent possible, the IRO shall perform this work using automated database inquiries.

Part Two of Reported Prices Procedures for BP

The IRO will obtain the following information:

- a) the five Medicaid rebate eligible NDCs for which King paid the largest amount (<u>i.e.</u>, total dollars) of Medicaid rebates for the Reporting Period;
- b) for each of the five Medicaid rebate eligible NDCs selected, obtain a copy of the internal King report(s) that identifies for each of the selected NDCs all unique prices lower than the reported BP for the selected quarter that existed within King's systems used to determine BP; and
- c) for each unique price lower than the reported BP identified in the applicable report(s), the IRO will review a minimum of five randomly selected contracted transactions associated with each of those unique lower prices (or, if there are fewer

than five such transactions, all such transactions) to assess if each was properly excluded from the determination of BP for that Medicaid rebate eligible NDC in the quarter under review in accordance with King's stated methodology and/or policies and procedures.

3. Additional Investigations

If the IRO identifies any prices reviewed in Part One or Part Two of the Reported Prices Procedures for BP that were not accurately reflected in King's systems and/or were not appropriately included in, or excluded from, King's BP determination in accordance with King's policies, procedures, and methodologies, such prices shall be considered an error. The IRO shall conduct such Additional Investigation as may be necessary to determine the root cause of the error. For example, the IRO may need to review additional documentation, conduct additional interviews with appropriate personnel, and/or review additional contracts to identify the root cause of the error.

Upon completion of this review and Additional Investigation, if warranted, the IRO will report to the OIG its findings relating to any errors and their root cause(s).

In the event the IRO finds more than one error for the quarter under review in Part One or Part Two testing, the IRO will perform a second set of Part One or Part Two testing procedures (i.e., Part One or Part Two testing depending which Part of the Reported Prices Procedures for BP resulted in an Additional Investigation being warranted) for the same quarter and population of data after King has submitted its management response to the IRO findings to the OIG, after the OIG has reviewed and considered King's management response, and the OIG has determined that additional Part One or Part Two testing is warranted following consultations with King and the IRO.

Should it be determined that additional Part One or Part Two testing is warranted, the IRO shall:

a) If additional Part One testing is required, test a random selection of an additional five King Customers and contract

prices associated with those Customers from the large King Customer pool; and/or

b) If additional Part Two testing is required, test the next five Medicaid rebate eligible NDCs with the highest amounts of Medicaid rebates (total dollars) paid by King.

B. Reported Prices Procedures for AMP

1. The IRO shall select AMPs that were reported to CMS for five products for the selected quarter. The selected NDCs shall be: (i) the three NDCs for which King paid the largest amount (i.e., total dollars) of Medicaid rebates in the Reporting Period and (ii) two NDCs selected at random (collectively, the "Selected AMP NDCs"); provided that if King paid less than \$20,000 in Medicaid rebates in the Reporting Period for any randomly selected NDC, the IRO will replace such NDC with a randomly selected NDC for which King paid at least \$20,000 in Medicaid rebates in the Reporting Period.

The IRO shall randomly select 50 transactions (sales transactions and price concessions) associated with each of the five selected AMPs. More specifically, the IRO shall review 25 transactions that were included from the calculation of AMP and 25 transactions that were excluded from the calculation of AMP. This review shall determine, in accordance with King's policies, procedures, and methodologies, whether: 1) each transaction is supported by source documentation; and 2) the transaction was appropriately included or excluded from the AMP under review.

2. Additional Investigations

If the IRO identifies any transactions that were not supported by source documentation and/or were not appropriately included in, or excluded from, the calculation of AMP in accordance with King's policies, procedures, and methodology, such transactions shall be considered an error. The IRO shall conduct such Additional Investigation as may be necessary to determine the root cause of the error. For example, the IRO may need to review additional documentation, conduct additional interviews with appropriate personnel, and/or review additional contracts to identify the root cause of the error.

Upon completion of this review and Additional Investigation, if warranted, the IRO will report to the OIG its findings relating to any errors and their root cause(s).

In the event the IRO finds more than one error for the quarter under review, the IRO will perform a second set of review procedures relating to the AMP calculations for the same quarter and population of data as in the first review. These additional review procedures will be developed in consultation with the OIG after King has submitted its management response to the IRO findings to the OIG, after the OIG has reviewed and considered King's management response, and the OIG has determined that additional testing is warranted.

C. <u>Medicaid Drug Rebate Transactions Report</u>

The IRO shall prepare a report annually based upon each Medicaid Drug Rebate Transaction Engagement performed. The report shall contain the following general elements pertaining to the Reported Prices Procedures for AMP and the Reported Prices Procedures for BP (Part One and Part Two):

- 1. Testing Objective a clear statement of the objective(s) intended to be achieved by each part of the Reported Prices Procedures;
- 2. Testing Protocol a detailed narrative description of: (a) the procedures performed; (b) the sampling units; and (c) the universe from which the sample was selected; and
- 3. Sources of Data a full description of documentation and/or other relevant information relied upon by the IRO when performing the testing.

The IRO's report shall include the following results for each engagement:

The Reported Prices Procedures for AMP

- a) a list of the five AMPs reported to CMS that were selected by the IRO for review, a descriptive list of the 50 selected transactions associated with each reported AMP, and the underlying documentation supporting the random selection of the AMPs and the transactions;
- b) a description of the steps taken and the supporting documentation reviewed to assess whether: 1) supporting documentation exists for each of the selected transactions; and 2) each selected transaction was appropriately included in, or excluded from, the AMP calculation in accordance with King's policies, procedures, and methodologies;
- c) a list of any transactions not supported by source documentation and/or not appropriately included in, or excluded from, King's AMP calculation; a description of any adjustments to AMP reported to CMS; and a description of any additional follow-up action taken by King;
- d) a detailed description of any Additional Investigation or review undertaken with regard to any transactions that were not supported by source documentation and/or were not appropriately included in, or excluded from, King's AMP calculation and the results of any such investigation or review; and
- e) the IRO's recommendations for changes in King's policies, procedures, and/or methodology to correct or address any weaknesses or deficiencies uncovered during the review.
- The Reported Prices Procedures for BP Part One
 - a) a list of the 20 King Customers selected under Part One, the number of contracts associated with each King Customer; the NDCs tested; the contract prices for each NDC tested; a list of any supporting documentation reviewed;
 - a description of the IRO's stratification system for identifying the "large" and "small" customers and documentation supporting the random selection of the customers;

- c) for each selected King Customer, a description of the steps taken to test that the contract price(s) for each NDC selected was accurately reflected in King's systems;
- d) for each selected King Customer, the results from testing whether each NDC contract price was accurately reflected in King's contracting systems. If the correct price was not reflected in the systems, the IRO should identify the correct price term;
- e) a detailed description of any Additional Investigation or review undertaken with regard to any price not accurately reflected in King's systems and the results of any Additional Investigation or review undertaken with respect to any such price;
- f) for each selected King Customer, a description of the steps taken to test that each contract price term was appropriately considered in King's determination of BP for that NDC in accordance with King's policies, procedures, and methodologies;
- g) for each selected King Customer, a list of any price inappropriately included in, or excluded from, King's BP determination for that quarter based on King's policies, procedures, and methodologies; a description of any adjustments to BP reported to CMS; and a description of any additional follow-up action taken by King;
- h) a detailed description of any Additional Investigation or review undertaken with regard to any price not appropriately included in, or excluded from, King's BP determination for the selected quarter, and the results of any Additional Investigation or reviews undertaken with respect to any such price; and
- the IRO's recommendations for changes in King's policies and procedures and/or methodology to correct or address any weaknesses or deficiencies uncovered during the review.
- 3. The Reported Prices Procedures for BP Part Two

- a) a narrative list of the five Medicaid rebate eligible NDCs with the highest rebates paid by King for the quarter under review and the BP reported by King to the Medicaid Drug Rebate Program for each of the five NDCs for the quarter under review, and the underlying documentation supporting the random selection of the five NDCs;
- b) a description of the steps and the supporting documentation reviewed to assess the unique lower prices identified in the King report(s) for each of the selected NDCs, which were below BP reported by King to CMS in the quarter. If more than five contracted transactions are associated with any of the unique lower prices, the IRO shall also identify how many such transactions exist for each unique lower price;
- c) a list of any prices not included in, or excluded from, King's BP determination for that quarter in accordance with King's policies, procedures and methodology; a description of any adjustments to BP reported to CMS; and a description of any additional follow-up action taken by King;
- d) a detailed description of any Additional Investigation or review undertaken with regard to any prices that were not accurately included in, or excluded from, King's BP determination for the quarter under review and the results of any such investigation or review; and
- e) the IRO's recommendations for changes in King's policies, procedures, and/or methodology to correct or address any weaknesses or deficiencies uncovered during the review.

Appendix C

Certification for CIA with King Pharmaceuticals, Inc.

CERTIFICATION

In accordance with the Corporate Integrity Agreement (CIA) entered between King Pharmaceuticals, Inc. (King) and the OIG, the undersigned hereby certifies the following to the best of my knowledge, information, and belief:

- King has in place policies and procedures describing in all material respects the methods for collecting, calculating, verifying and reporting the data and information reported to the Centers for Medicare and Medicaid Services (CMS) and/or the State Medicaid programs in connection with the Medicaid Drug Rebate program (Medicaid Rebate Policies and Procedures);
- 2) the Medicaid Rebate Policies and Procedures have been designed to ensure compliance with King's obligations under the Medicaid Drug Rebate Program; and
- 3) King's Medicaid Rebate Policies and Procedures were followed in all material respects in connection with the calculation of Average Manufacturer Price and Best Price for King's products for each of the following four quarters: [specifically identify each quarter].

Frederick Brouillette, Jr.	
Corporate Compliance Office	er
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Date	